PCT/CH 2004/000480

SCHWEIZERISCHE EIDGENOSSENSCHAFT
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Bescheinigung

Die beiliegenden Akten stimmen überein mit den ursprünglichen Unterlagen der auf den nächsten Seiten bezeichneten, beim unterzeichneten Amt als Anmeldeamt im Sinne von Art. 10 des Vertrages über die internationale Zusammenarbeit auf dem Gebiet des Patentwesens (PCT) eingegangenen Patentanmeldung.

Attestation

Les documents ci-joints sont conformes aux pièces originales relative à la demande de brevet spécifiée aux pages suivantes, déposées auprès de l'Office soussigné, en tant qu'Office récepteur au sens de l'article 10 du Traité de coopération en matière de brevets (PCT).

Confirmation

It is hereby confirmed that the attached documents are corresponding with the original pages of the international application, as identified on the following pages, filed under Article 10 of the Patent Cooperation Treaty (PCT) at the receiving office named below.

Berne, le 02 août 2004

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Patentverfahren
Administration des brevets
Patent Administration

Rolf Hofstetter

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PCT REQUEST

147-13.B.WO

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0	**For receiving Office use only**	
0-1	International Application No.	PCT/CH 03 / 00527
0-2	International Filing Date	31. Juli 2003 (31.07.03)
0-3	Name of receiving Office and "PCT International Application"	RO / CH - Internationale Anmeldung PCT
0-4	**Form - PCT/RO/101 PCT Request**	
0-4-1	Prepared using	PCT-EASY Version 2.92 (updated 01.07.2003)
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	Swiss Federal Intellectual Property Institute (RO/CH)
0-7	**Applicant's or agent's file reference**	147-13.B.WO
I	**Title of invention**	A SYSTEM FOR PERFORMING PERITONEAL DIALYSIS
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V	**Designation of States**	
V-1	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AP: GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT EP: AT BE BG CH&LI CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT RO SE SI SK TR and any other State which is a Contracting State of the European Patent Convention and of the PCT OA: BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT
V-2	National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH&LI CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW
V-5	**Precautionary Designation Statement** In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.	
V-6	**Exclusion(s) from precautionary designations**	NONE
VI	**Priority claim**	NONE
VII-1	**International Searching Authority Chosen**	European Patent Office (EPO) (ISA/EP)

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VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	
IX	**Check list**	number of sheets	electronic file(s) attached
IX-1	Request (including declaration sheets)	5	-
IX-2	Description	13	-
IX-3	Claims	7	-
IX-4	Abstract	1	EZABST00.TXT
IX-5	Drawings	29	-
IX-7	TOTAL	55	
	Accompanying items	paper document(s) attached	electronic file(s) attached
IX-8	Fee calculation sheet	✓	-
IX-17	PCT-EASY diskette	-	Diskette
IX-19	**Figure of the drawings which should accompany the abstract**	3	
IX-20	**Language of filing of the international application**	English	
X-1	**Signature of applicant, agent or common representative**		
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10-2	**Drawings:**	
10-2-1	Received	
10-2-2	~~Not received~~	
10-3	**Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application**	
10-4	**Date of timely receipt of the required corrections under PCT Article 11(2)**	
10-5	**International Searching Authority**	ISA/EP
10-6	**Transmittal of search copy delayed until search fee is paid**	

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11-1	**Date of receipt of the record copy by the International Bureau**	

A system for performing peritoneal dialysis

Field of the invention

The present invention relates to systems for performing peritoneal dialysis on a patient and more precisely to such systems which include a liquid distribution system forming a distinct element.

State of the art

Peritoneal dialysis systems as defined above are described in the following patent documents : EP 0 790 841 B1, EP 0 695 397 B1, EP 0 852 953 B1, EP 0 694 125 B1, EP 0 686 237 B1, EP 0 471 000 B1, EP 0 332 690 B1, EP 0 262 182 B1, EP 0 259 464 B1 and EP 1 195 171 A2.

Summary of the invention

An objective of the present invention is to provide an improved peritoneal dialysis system and in particular an improved liquid distribution system.

This objective and many others are achieved with the system as defined in claim 1 and 38.

Preferred embodiments of the invention are defined in dependent claims 2 to 37 and 40 to 46.

Several advantages result from the invention, in particular :

- simpler, and therefore more efficient, liquid distribution system which may include only two distinct cavities,
- possibility to use a peristaltic pump, in particular a rotatable peristaltic pump,
- possibility to use an unidirectional pump which results in a higher precision and a longer life time,
- possibility to fix the liquid distribution system and the pump together, alternatively with vibration attenuating means,
- possibility to use a flexible membrane which covers the chambers and which include valve elements,
- the membrane may be molded,
- part of a pressure sensor can be incorporated in the membrane.

Those and other advantages will be better understood in the detailed description of the invention exemplified here below, together with the following figures.

Short description of the figures

Figure 1 shows in a schematic way the principle of the invention

Figure 1A shows the "fill" phase

Figure 1B shows the "drain" phase

Figure 2 illustrates a first embodiment of the invention (liquid distribution system)

Figure 3 illustrates a second embodiment (disposable cartridge) including a warmer chamber

Figure 4 shows the embodiment of figure 3 in a transparent view

Figure 5 shows the back side of the embodiment of figure 3 (disposable cartridge)

Figure 6 illustrates the disposable cartridge of figure 3 with the complete tubing set

Figure 7 shows an embodiment with the rotative parts (rollers) integrated on the cycler

Figure 8 shows the embodiment of figure 7 without the rollers

Figure 9 the disposable cartridge in two parts allowing to absorb pump vibrations

Figure 10 shows a cycler without the cartridge insertion slot

Figure 11 illustrates a disposable cartridge opened showing the peritoneal pump

Figure 12 is an upper view of an elastic molded membrane

Figure 13 is a bottom view of the membrane of figure 12

Figure 14 shows a membrane clipping system

Figure 15 shows the cycler of figure 10 in an open state

Figure 16 shows a cartridge loader

Figure 17 shows the cycler of figure 10, the insertion slot opened with the cartridge

Figure 18 shows the cycler of figure 10, the insertion slot closed with the cartridge

Figure 19 shows a front view of a valve

Figure 20 shows a front view of a pressure sensor

Figure 21 shows a pump race

Figure 22 shows a valve actuator and a membrane clipping system

Figure 23 shows a warmer

Figure 24 shows a warmer casing

Figure 25 is a table showing drain profiles

Numerical references used in the drawings

1. Pump
2. Liquid distribution system (cartridge)
3. Supply means (bag)
4. Patient
5. Patient line
6. Drain collector
7. First hub chamber
8. Second hub chamber
9. Liquid supply port with valve
10. Patient port with valve
11. Drain port with valve
12. Roller separator
13. Membrane
14. Membrane frame
15. Pressure sensor cavity (patient)
16. Patient port with valve (warmer chamber)
17. Warmer chamber
18. Patient port with valve (first hub chamber)
19. Warmer port
20. Roller element
21. Pump race
22. Roller
23. Tube connector for warming enter line
24. Liquid supply line
25. Drain line
26. Pump inlet
27. Pump outlet
28. Warmer pouch

29. Warmer enter line
30. Warmer exit line
31. Membrane pressure sensor area
32. Retaining element for pressure sensor
33. Clip cavity
34. Actuator
35. Clip plunger
36. Pressure sensor cavity (first hub chamber)
37. Pump flexible tube
38. Warmer port with valve
39. Membrane actuator clip
40. Membrane pressure volute
41. Cartridge loader
42. Pump motor + coder
43. Air sensor
44. Pressure sensor
45. Pump casing
46. Cartridge loader shaft
47. Cartridge loader frame
48. Cartridge loader linear cam
49. Cartridge loader motor
50. Cartridge insertion slot
51. Cycler
52. Cartridge motor shaft
53. Tube connector for supply line
54. Tube connector for drain line
55. Tube connector for warmer exit line
56. Pump enter line
57. Pump exit line
58. Sensor pressure housing
59. Sealing flange

Detailed description of the invention

The peritoneal dialysis system according to the invention is shown in a schematic way in figure 1. It includes a pump **1**, a liquid distribution system **2** (also named cartridge) comprising a first hub chamber **7** and a second hub chamber **8**. The first chamber **7** includes a pump inlet **26** connected to the pump **1** via a pump enter line **56**, a liquid supply port **9** with valve connected to supply means, e.g. to bags **3**, via a liquid supply line **24** and a patient port **10** with valve connected to a patient **4** via a patient line **5**. The second chamber **8** includes a pump outlet **27** connected to the pump **1** via a pump exit line **57**, a drain port **11** with valve connected to a drain collector **6** via a drain line **25** and a patient port **18** with valve connected to a patient **4** via a patient line **5**.

Figure 1A shows the "fill" phase where liquid is supplied to the patient **4** from and through the following elements : Bag **3** – Liquid supply line **24** – (open) liquid supply port **9** – First chamber **7** – Pump inlet **26** - Pump enter line **56** – Pump **1** – Pump exit line **57** – Pump outlet **27** – Second chamber **8** – (open) Patient port **18** – Patient line **5** – Patient **4**.

Figure 1B shows the "drain" phase where liquid is drained from and through the following elements : Patient **4** – Patient line **5** – (open) Patient port **10** – First chamber **7** – Pump inlet **26** – Pump enter line **56** – Pump **1** – Pump exit line **57** – Pump outlet **27** – Second chamber **8** – (open) Drain port **11** – Drain line **25** – Drain collector **6**.

The embodiment illustrated on figure 2 shows an assembly constituted by a pumping element **1** and a cartridge **2**. Both elements are fixed together but may be separated. Figure 21 shows a better view of the fixation between both elements. Preferably, the pumping element **1** is fixed to the cartridge **2** by

vibration attenuation means in order to minimize the vibration on cartridge **2** when the pump is operating.

The upper face of the cartridge contains a first hub chamber **7** , a second distinct hub chamber **8** and a cavity **15** which forms part of a pressure sensor. The first chamber hub chamber **7** has three liquid supply ports **9**, one patient port **10**, one pump inlet **26** and a cavity **36** which forms part of a pressure sensor. The second hub chamber **8** has a patient port **18**, a drain port **11** and a pump outlet **27**.
The pumping element **1** comprises a pump casing **45** which contains three rollers **22** maintained around the pump casing center by a roller separator **12**. The space between the roller-roller separator element and the pump casing defines a pump race **21** in which a flexible tube **37** is placed. The flexible tube being connected with the pump enter **56** and exit **57** lines. The rollers **22** may be motor driven by a shaft **52** (not shown on figure 2) in such a way as to progressively compress the flexible tube **37** resulting thereby in a peristaltic movement along the flexible tube **37**.

During the "fill" phase, liquid is supplied via one tube connector **53** and liquid supply port **9** to the first hub chamber **7**. It then enters the pump **1** through the pump inlet **26**, moves along the flexible tube **37**, enters the second hub chamber **8** through the pump outlet **27** and goes to the patient **4** via patient port **18** and patient line **5**.

During the "drain" phase, liquid leaves the patient **4**, enters the first hub chamber **7** via patient port **10**. It then enters the pump **1**, moves along the flexible tube **37**, enters the second hub chamber **8** and goes to the drain collector **6** via drain port **11**, drain tube connector **54** and drain line **25**.

It should be noted at this stage that each bag **3** may contain a specific liquid.

The cartridge **2** of figure 3 is identical to the cartridge of figure 2 with the exception of an additional cavity, namely a warmer chamber **17**, which includes a warmer port **19** and a patient port **16**. The warmer port **19** is connected to a warmer **28** (not shown on figure 3) via a warmer tube connector **55** and a warmer

exit line **30**. The patient port **16** is connected to the patient line **5**. The second hub chamber **8** contains a warmer port **38** connected to a warmer **28** (not shown on figure 3) via a warmer tube connector **23** and a warmer enter line **29**.

During the "fill" phase, liquid is supplied via one tube connector **53** and liquid supply port **9** to the first hub chamber **7**. It then enters the pump **1**, moves along the flexible tube **37**, enters the second hub chamber **8**, moves into the warmer **28** via warmer port **38**, enters the warmer chamber **17** via warmer port **19** through the tube connector **55** and goes to the patient **4** via patient port **16** and patient line **5**.

As it can be seen on the embodiments of figures 2 and 3, the pump **1** is unidirectional, i.e. whatever the pumping phase is, liquid in the flexible tube **37** always moves in the same direction. This feature provides several advantages. In particular a higher precision in the liquid exchange due to the same flow speed for both the fill and drain phases and a longer life time.

It is known that peristaltic pumps are usually accurate within +/- 5%. As such, peristaltic pumps cannot be used for peritoneal dialysis since the volume which is filled within the patient cavity requires to be drained in the same amount within +/- 2%, otherwise the peritoneal cavity could be overfilled (e.g. for 12 liters exchanged over the therapy, a 3% difference represents 360ml which is as much as 18% of the 2 liters contained in the peritoneal cavity for each cycle) and/or the ultra-filtration could be altered. In order to improve on the accuracy of the exchanged volume without requiring the construction of highly accurate pumps which would warranty a +/-2% accuracy, the invention provides a method whereby the conventional pump is used in a unidirectional way which insures the same accuracy for both the fill and the drain phase (usually within +/-2%) and therefore an appropriate balance of fluid. The volume filled with such a pump may be inaccurate within +/-5%, but since the same cassette with the same flow speed characteristics (namely the same flow direction) is used, the balance can be insured within +/-2% as required for the therapy. If the cassette would be used in both directions, the difference in flow speed would be within +/-5% due to the non parallel behavior of peristaltic pumps, in particular over time.

It should be noted that with the present invention, the precision in the liquid exchange is maintained even if the pump flow rate changes after a certain time due to aging of the tubing since the fill and drain are operated within a time window which is small in comparison to the time in which the flow speed is altered by aging (e.g. a flow alteration of the pump of approximately 1% per 20 liters of fluid pumped, with exchanged volumes of approximately 2 liters per cycle). In addition, the use of the cassette in one direction enables a better control over the aging of the tubing and, therefore, a better prediction of the impact on the pumping accuracy.

Figure 4 is a transparent view of the cartridge which better shows how the different elements are connected. A cartridge bottom view is shown on figure 5. The tubing system in the lower face and the cavities of the upper face are all made within one single part, e.g. an injected part of plastic material.

Figure 6 shows an assembly including the cartridge **2** of figure 3 fixed to a pumping element **1**, a patient line **5**, supply bags **3**, a warmer enter line **29**, a warmer outer line **30** and a warmer pouch **28** which is essentially made of a fluid circuit within a plastic bag (e.g. PVC) to be put into contact with a warming plate.

Figure 6" shows a warming plate contained into a warming system where the warming pouch has a shape of a sock to be inserted onto the warming plate. The warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.

Figure 7 shows a cartridge identical to the one of figure 3 where the rollers are part of the cycler rather than of the cartridge. In this embodiment, the pumping element **1** which only contains the tube and tubing race and the cartridge **2** are forming a single element.
The rollers, which are part of the cycler and therefore re-usable rather than disposable with the cardridge, have a conical shape so as to allow the rollers to

be self inserted in the pump race. In this configuration the cartridge is more simple to manufacture and contains less parts. No other insertion mechanism is required, since the tube is automatically compressed on the race while the rollers are penetrating into the cartridge. As a separate matter, the use of conical rollers **22** results in a more constant speed of the liquid along the flexible tube **37**.

Figure 8 shows the assembly of figure 7 without the rollers **22** and the roller element.

Of course, other roller shapes may be used, e.g. spherical or cylindrical.

The embodiment of figure 9 only differs from the one of figure 8 in that the pump casing **45** is made out of two parts with an interface between the pumping element **1** and the cartridge **2**. This configuration offers an improved assembly process of the pump and the possibility to add means to limit the propagation of the vibrations from the pump **1** to the cartridge **2**.

Figure 10 shows a cycler **51** without cartridge **2** and pumping element **1**. It contains a driving zone which includes a motor shaft **52** for the rollers **22** and several actuators **34**. The cycler **51** also includes an air sensor **43** situated close to the patient line **5** when the cartridge **2** is inserted. The air sensor may be made of a piezo emitter and a piezo receiver.

Figure 11 represents the embodiment of figure 2 with a flexible membrane **13** covering the hub chambers **7,8** and the pressure sensor cavity **15**.
The upper face of the membrane **13** (see figure 12) contains several valve elements having a cylindrical cavity **39** and a pressure sensor area **31** with a ply **40** around its periphery. The valve elements **39** are designed to tightly close the ports when the membrane **13** moves downwardly.
On its bottom face (see figure 13) the membrane **13** contains a semi-circular flange **32** around the pressure sensor area and annular liquid tight joints.

In addition the cartridge **2** includes liquid tight joints arranged in such a manner that they allow a liquid tight connection between the cartridge **2** and the membrane **13**.

Advantageously the membrane is molded. Preferably the membrane **13** is made of silicone.

The membrane **13** is press-fitted to the cartridge **2** along its periphery with a membrane frame14 (see figure 14).

Figure 15 shows the cycler of figure 10 in an open state which includes a pump motor and a coder **42**. The rectangle **41** represents the cartridge loader.

Figure 16 shows a cartridge loader comprising cartridge loader shafts **46**, a cartridge loader frame **47**, a cartridge loader linear cam **48** and a cartridge loader motor **49**. On this figure, the two displacement parts **48'** and **48"** represent two different positions of the loader in an open and closed position only for explanation reasons.

The cartridge loading mechanism allows a tight connection between the membrane and the valves and the cartridge. In order to insure proper positioning of the cartridge onto the valve actuators, as well as pressure sensor and air sensor onto the right place, the cartridge is maintained into the loading mechanism which progressively moves the cartridge in an axis which is perpendicular to its surface. By the same movement, the axis or the rollers can be inserted in the right position to ensure proper functioning of the pump. The same movement can also insure appropriate pressure on the surfaces which requires to be maintained together, such as for tightness control on the membrane and/or tubing of the pump.

Figure 17 shows the cycler **51** of figure 10 containing a cartridge **2**. The cycler **51** has an insertion slot **50** in an open position.

Figure 18 shows the same cycler **51** but with an insertion slot in a closed position.

Figure 19 represents an actuator **34** with its plunger **35** clipped in its corresponding valve element **39** of the membrane. The actuator **34** may be a

magnet or an electromagnetic element. The plunger **35** and the valve element **39** are designed to move together when the actuator is activated.

Figure 22a and 22b shows the plunger **35** and the valve element **39** in a separate position (fig. 22a) before insertion and in an activated position (fig. 22b) after insertion. One embodiment of the invention is to insure a proper insertion of the actuator head into the membrane clipping part by having the length of the part of the actuator head to be inserted into the clip of the membrane to be longer than the possible displacement of the actuator head, so as to ensure that the actuator head is always properly inserted into the clip of the membrane. As such, in the worst case where the actuator head would be fully retracted within the actuator during the clipping translation into the membrane, the actuator head would pass the clipping equilibrium position before the end of the translation, so that the remaining translation will ensure clipping of the actuator head into the membrane.

The front view of figure 20 illustrates a pressure sensor **44** which may be used with the independent pressure sensor cavity **15** of the cartridge **2** or with the pressure sensor cavity **36** of the first hub chamber **7**. The ply **40** makes the pressure sensor less sensitive to the elasticity of the membrane **13** in the sensor pressure area. In addition, the shape of the cavity **15** shall be made such that air can be eliminated easily when fluid is passing into the cavity (e.g. by having a round shaped bottom of the cavity within the direction of the flow).

In the embodiments discussed previously, each port has a dedicated valve. This is not the case for the pump inlet and the pump outlet which are always kept open.

The invention encompasses several other features not necessarily illustrated on the figures. For instance, the cycler or the cartridge-pumping element assembly may contain a window for detecting correct positioning of the flexible tube of the pump as shown in figure 21 (circle).

When the system functions, the pressure is preferably always maintained positive with respect to the drain. This is a safety measure which avoids said contaminated liquid to potentially infect the patient.

Advantageously the liquid pressure entering and exiting the cartridge is sensed and, if necessary, the pump flow rate is corrected in accordance with the pressure difference. This pressure difference is better calculated at the initial priming phase of the system, where the pressure is directly related to the positioning of the liquid bags **3** and the patient position relative to the cycler.
Alternatively or in addition, the pump flow rate may be regulated according to a predetermined deterioration of the tubing which is known from the characteristics of the tubing.

The drain phase may be limited as to its duration in function of the drain speed, the drain speed having to be reduced when the patient peritoneal cavity pressure decreases, typically between 30 ml/min and 120 ml/min instead of a nominal 200 ml/min speed. This feature is particularly interesting because the dialysis efficiency is directly related to the time the liquid stays in the peritoneal cavity and the duration required to fully drain the peritoneal cavity may limit this time without a significant impact with regard to the peritoneal fluid characteristics. As such, one method of the invention would be to determine at which speed it is not worth continuing draining the patient entirely and rather fill the patient with fresh fluid, taking into consideration the remaining fluid volume in the peritoneal cavity which has not been expelled and expected ultra-filtration additional volume to avoid overfill. The cycles will therefore be all different, based on reaching a pre-determined drainage speed or a pre-determined decrease profile of the drainage speed, so that the efficient time of dialysis will be increased. An example of drainage speed on a patient is given in the figure **25**, where, for each column which is divided in three parts, the upper part corresponding to a limit of drainage speed at which it is, for example, not worth continuing the drainage even if the next fill volume will not be a full fill. In comparison to actual method where a tidal at (e.g. 80%) is preset, the method under the invention is adapting each drainage to the actual drainage speed, trying to empty as much as possible without

compromising on the efficacy of the peritoneal dialysis. Of course some limits can be set, where a minimum of drainage volume has to be reached before such a limitation takes place for each cycle.

Another method under the present invention consists to fill always as much volume, within certain limits to be set for the patient, until a certain pressure in the peritoneal cavity is reached. As such, the peritoneal dialysis can be improved since the efficiency is related to the amount of fluid filled at every cycle. According to such method, the pump shall fill the patient until a certain pressure is reached (e.g. 10cm water) and stop only once such pressure is reached or a certain maximum volume is reached. Accordingly, it is important to measure continuously the pressure during the dwell time to make sure that no over pressure is reached, such as due to the ultra-filtration. One possibility is also to always fill up to such a limited pressure and/or volume and drain at a certain interval thereafter a certain volume to compensate for expected ultra-filtration. Another possibility is to increase the ultra-filtration during the last cycle, by using e.g. low sodium concentrated solution.

Claims

1. A system for performing fluid administration on a patient comprising :
   - a liquid pump (1),
   - a liquid distribution system (2) connected to said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa,
   - liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1),
   - a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4),

   characterized by the fact that said liquid distribution system (2) comprises two distinct hub chambers (7,8), the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26) , the second hub chamber (8) including at least, one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27), said system furthermore comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa.

2. System according to claim 1 wherein said second hub chamber (8) furthermore includes at least one drain port with dedicated valve means (11), said control means being also arranged to close said patient port (18) of the second hub chamber (8) when said drain port (11) is open and vice versa.

3. A system according to claim 1 or 2 wherein said liquid distribution system (2) only includes two hub chambers (7,8).

4. A system according to anyone of the previous claims furthermore comprising a warmer system (28), a cavity (17) including a warmer port

(19) and a patient port (16), said patient port (18) of the second hub chamber (8) being connected to said warmer port (19) via said warmer system (28).

5. A system according to claim 4 wherein said warmer system (28) is a warmer in-line.

6. A system according to claim 5 wherein said warmer in-line comprises a warming plate contained therein, such warming plate being covered by a warming pouch like a sock.

7. A system according to claim 6 wherein said warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.

8. A system according to anyone of the previous claims wherein said first hub chamber (7) includes several liquid supply ports with respective valve means (9).

9. A system according to the previous claim wherein said liquid supply ports (9) are connected to respective liquid supply means having each a different kind of liquid.

10. A system according to anyone of the previous claims wherein said liquid pump is a peristaltic pump.

11. A system according to the previous claim wherein said peristaltic pump is unidirectional.

12. A system according to anyone of the previous claims wherein said liquid pump (1) is composed of a tubing and rolling surface on which the tubing is

compressed once the cartridge is inserted into a pumping device containing rollers.

13. A system according to the previous claim where said rollers (22) are of a conical shape in such a way as to be self inserted in the pump race, i.e. without any other mechanism.

14. A system according to claim 12 where said rollers are of a spherical shape.

15. A system according to anyone of the previous claims wherein said liquid pump (1) and said liquid distribution system (2) are fixed together to form a single cartridge.

16. A system according to the previous claim wherein said liquid pump (1) is fixed to said liquid distribution system (2) by vibration attenuation means in order to minimize the vibration on the liquid distribution system (2) when the pump is operating.

17. A system according to anyone of the previous claims wherein all hub chambers, including said ports and ports, are made within one single part.

18. A system according to the previous claim wherein said single part is an injected part of plastic material.

19. A system according to anyone of the previous claims wherein each hub chamber (7,8) is closed with an upper wall made of a flexible membrane (13), said membrane including valve elements (39) situated above each of said port or port with valve means, said valve elements (39) being designed to close said port or port when the membrane (13) moves downwardly.

20. A system according to the previous claim wherein said membrane is molded.

21. A system according to the previous claim wherein said membrane is made of silicone .

22. A system according to the previous claim wherein said membrane includes liquid tight joints.

23. A system according to anyone of the previous claims wherein said liquid distribution system includes liquid tight joints arranged in such a manner that they allow a liquid tight connection between said liquid distribution system and a membrane situated on it.

24. A system according to anyone of claims 19 to 22 wherein said membrane contains protruding elements designed for a liquid tight connection between said hub chambers.

25. A system according to claim 19 wherein each of said valve elements (39) is designed to be clipped to an actuator (34), e.g.. an electromagnetic actuator or a magnet, arranged above said membrane (13).

26. A system according to the previous claim wherein each of said valve elements comprises a cavity designed to receive and hold the plunger of an actuator, said cavity having an height which substantially corresponds to at least the valve displacement.

27. A system according to anyone of claim 19 to 26 wherein said membrane (13) is press-fitted along its external border to the liquid distribution system, the membrane (13) being furthermore held by a frame (14) .

28. A system according to anyone of claim 19 to 27 wherein said membrane (13) contains a portion (15) which is forming part of a pressure sensor.

29. A system according to the previous claim wherein the active area of said pressure sensor is designed to be more flexible than the remaining area.

30. A system according to claim 28 or 29 wherein said pressure sensor has the shape of a disc of which the periphery is gripped, said disc furthermore comprising an annular ply.

31. A system according to anyone of claims 28 to 30 wherein said pressure sensor is situated on the patient line, independently from said hub chambers.

32. A system according to anyone of claims 28 to 31 furthermore comprising a second pressure sensor, said second pressure sensor being in connection with the first hub chamber.

33. A system according to anyone of the previous claims wherein said liquid distribution system includes an air sensor situated on the patient conduit side.

34. A system according to anyone of the previous claims comprising a cartridge loading mechanism which allows a tight connection between the membrane and the valves and the liquid distribution system.

35. A liquid distribution system (2) for a system performing fluid administration on a patient as defined in anyone of the previous claims.

36. A pressure sensor for a system for performing fluid administration on a patient as defined in anyone of claims 28 to 34.

37. A system according to anyone of the previous claims furthermore comprising a window for detecting correct positioning of the tube.

38. Method of use of the system as defined in anyone of the previous claims wherein said patient port (10) is closed when said liquid supply port (9) is open and vice versa.

39. Method according to the previous claim wherein the pressure is always maintained positive with respect to the drain.

40. Method according to claim 38 or 39 wherein said liquid is always pumped in the same direction.

41. Method according to anyone of claims 38 to 40 consisting of sensing the liquid pressure entering and exiting the liquid distribûtion system and, if necessary, correct the pump flow rate in accordance with the pressure difference.

42. Method according to anyone of claims 38 to 41 consisting in regulating the pump flow rate according to a known predetermined alteration of the flow rate by aging of the tubing.

43. Method according to anyone of claims 38 to 42 wherein the drain phase is a function of the drain speed, said drain phase being ended when the speed is reaching a certain value based on the patient peritoneal cavity pressure measurement.

44. Method according to anyone of claims 38 to 43 wherein the peritoneal volume filled during a cycle is a function of the intra-peritoneal pressure.

45. Method according to the previous claim wherein the peritoneal cavity is partially emptied as soon as the pressure has reached a predefined threshold.

46. Method according to anyone of claims 38 to 45 consisting in the use of a low Natrium concentration liquid for the last exchange cycle to improve ultra-filtration.

47. Use of a system as defined in anyone of the previous claims for peritoneal dialysis.

Abstract

The invention concerns a system and a method of use of said system for performing fluid administration on a patient, the system comprising :
- a liquid pump (1),
- a liquid distribution system (2) connected to said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa,
- liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1),
- a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4),
the system being characterized by the fact that said liquid distribution system (2) comprises two distinct hub chambers (7,8), the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26) , the second hub chamber (8) including at least, one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27), said system furthermore comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa.

(Fig. No. 3)

Fig. 1

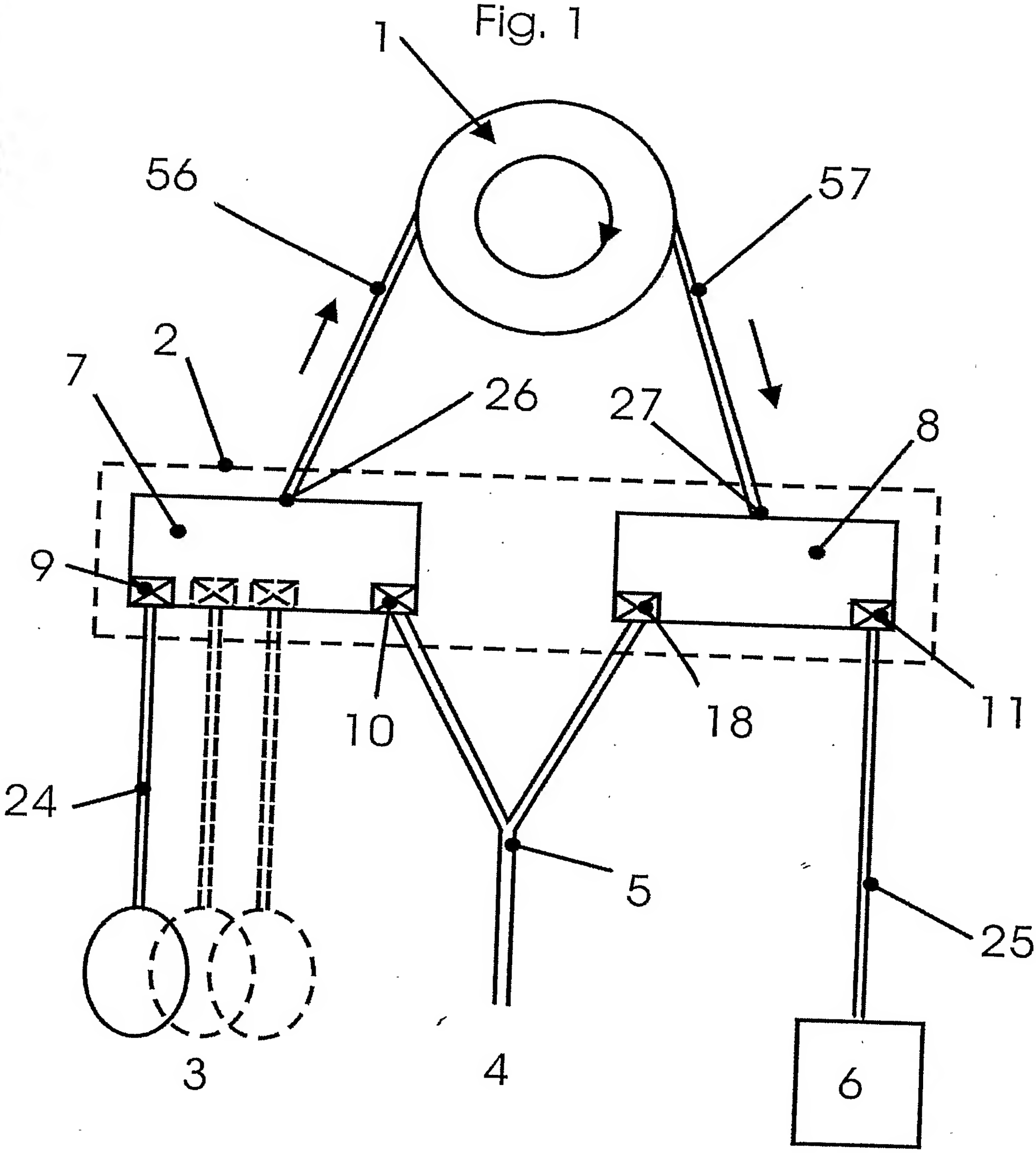

Fig. 1a

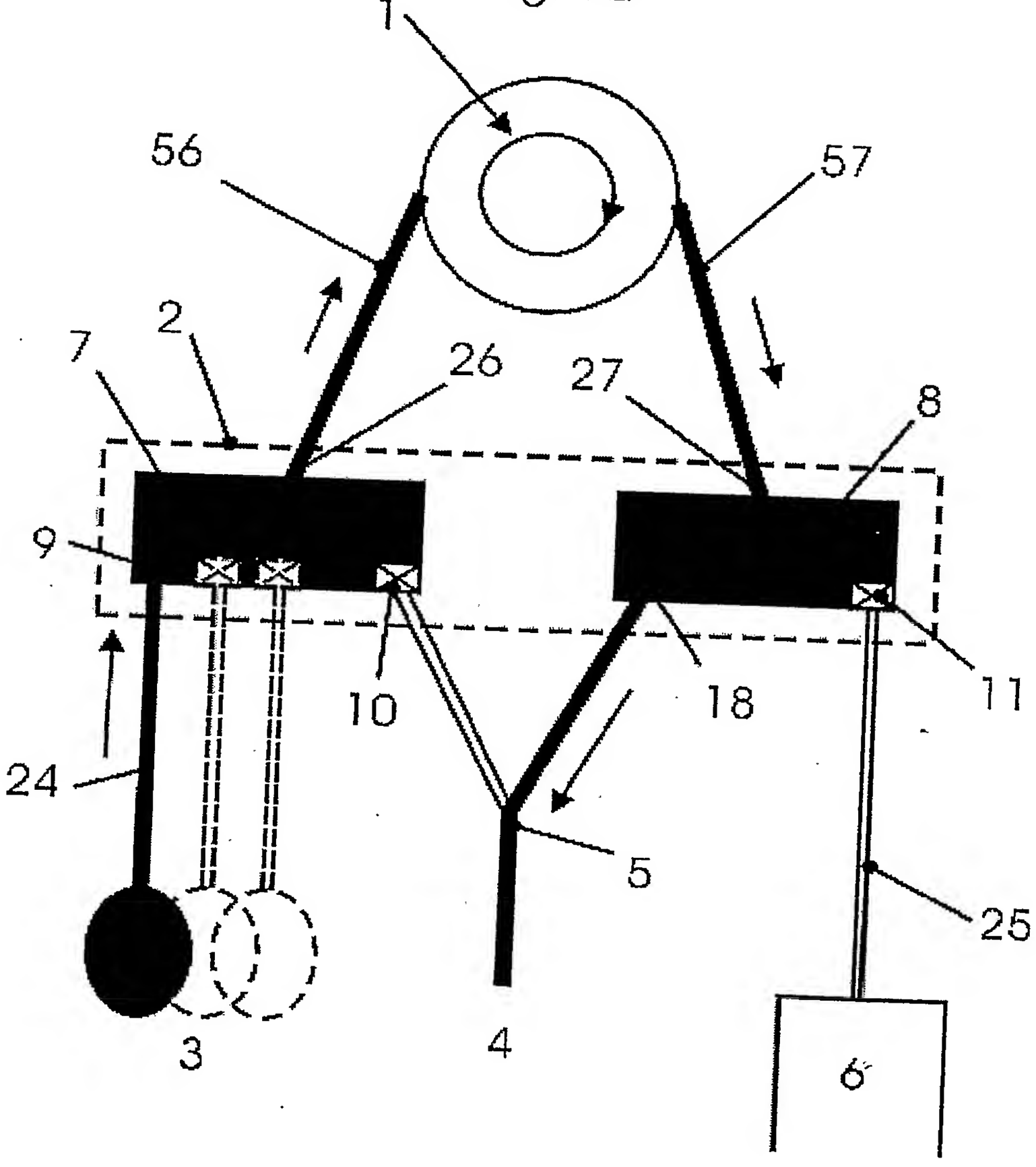

Fig. 1b

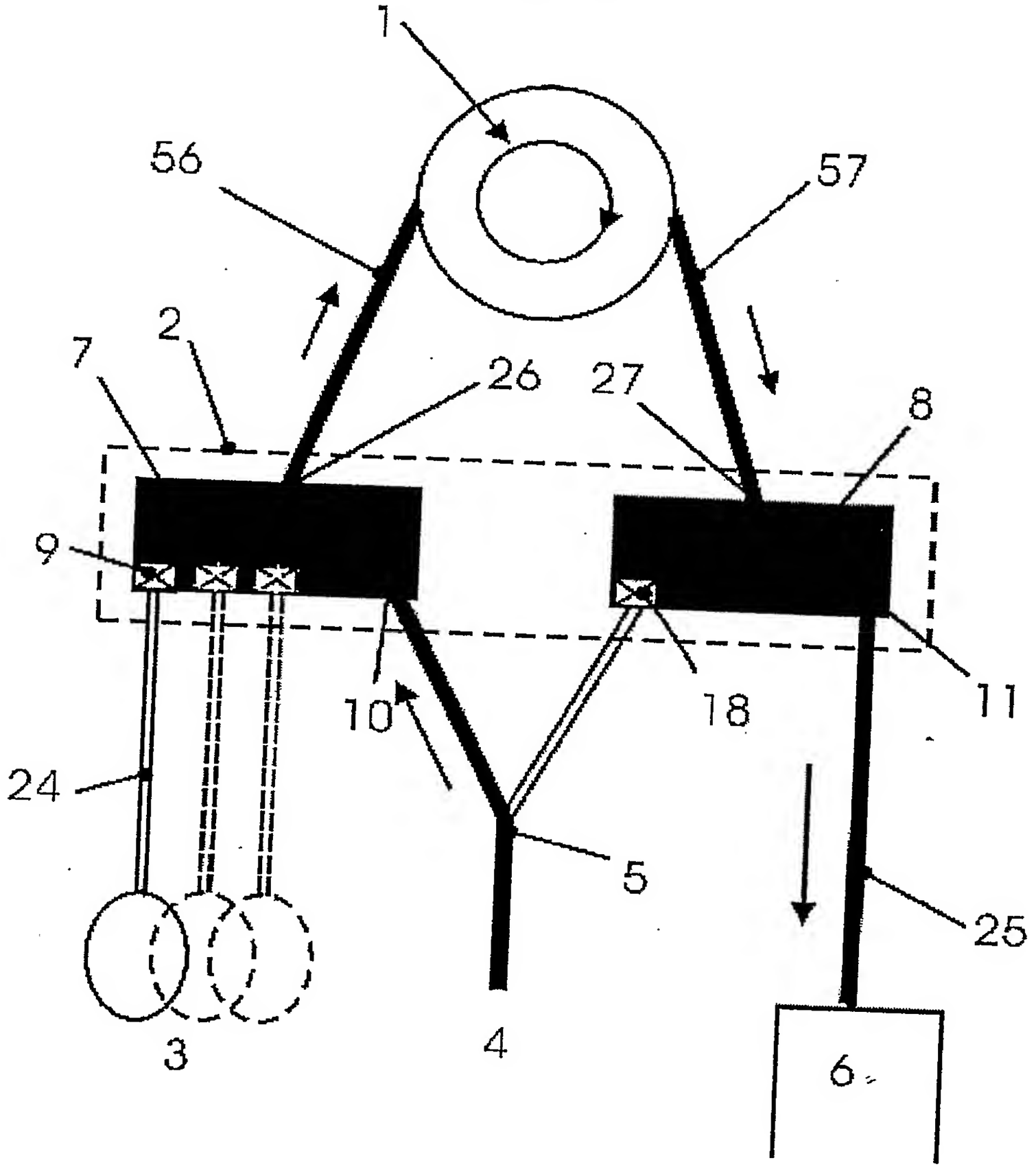

Fig. 2

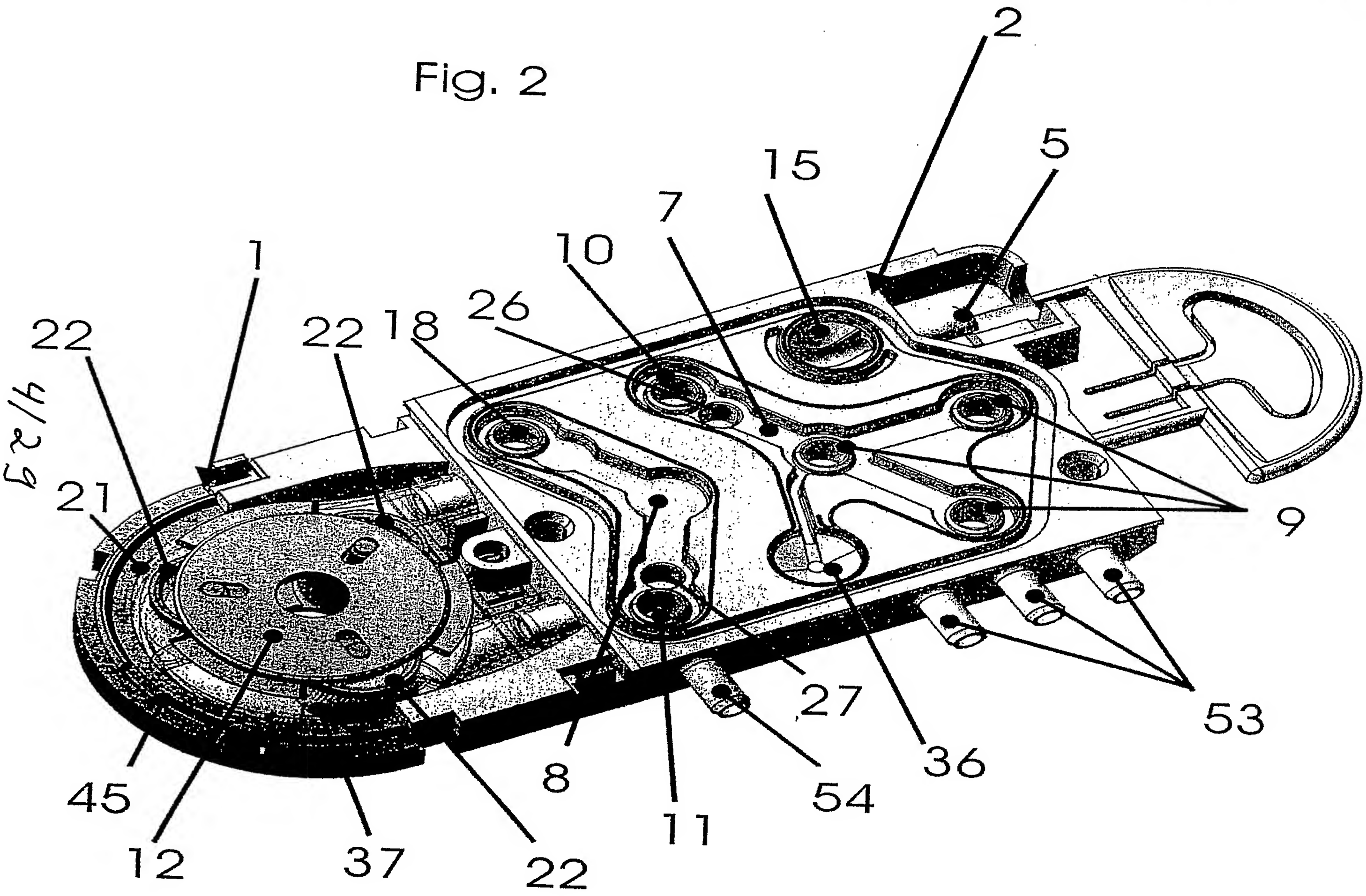

Fig. 3

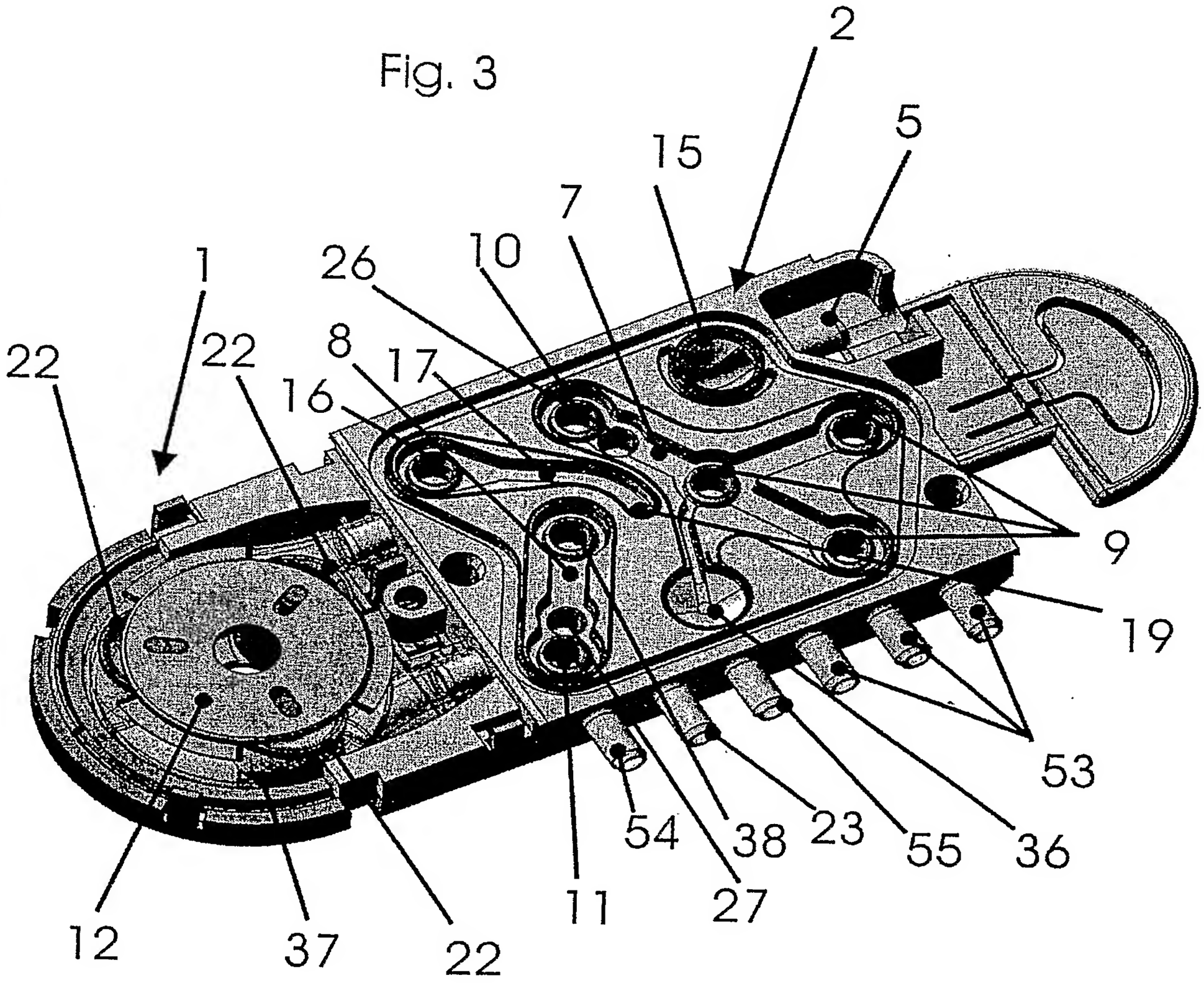

Fig. 4

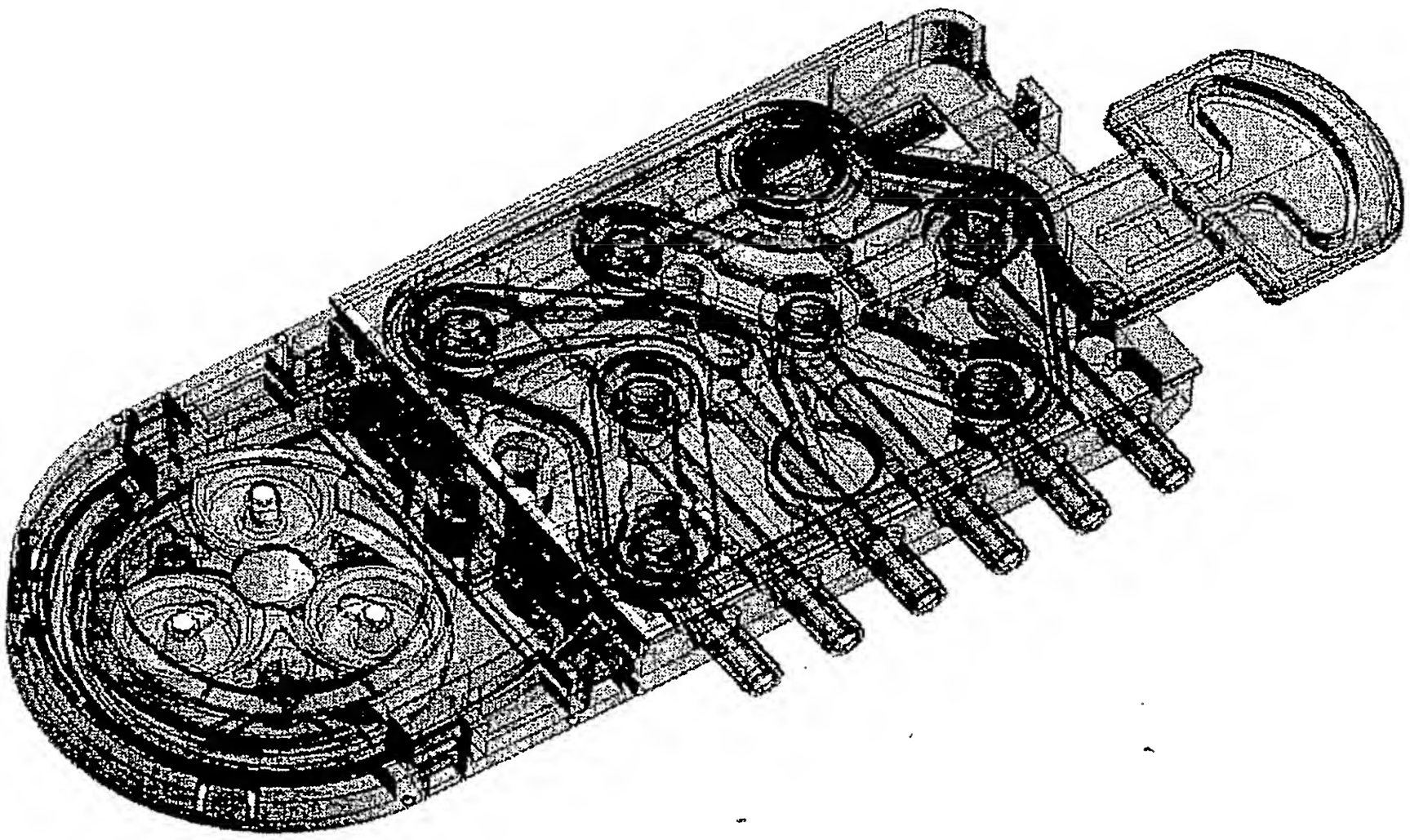

Fig. 5

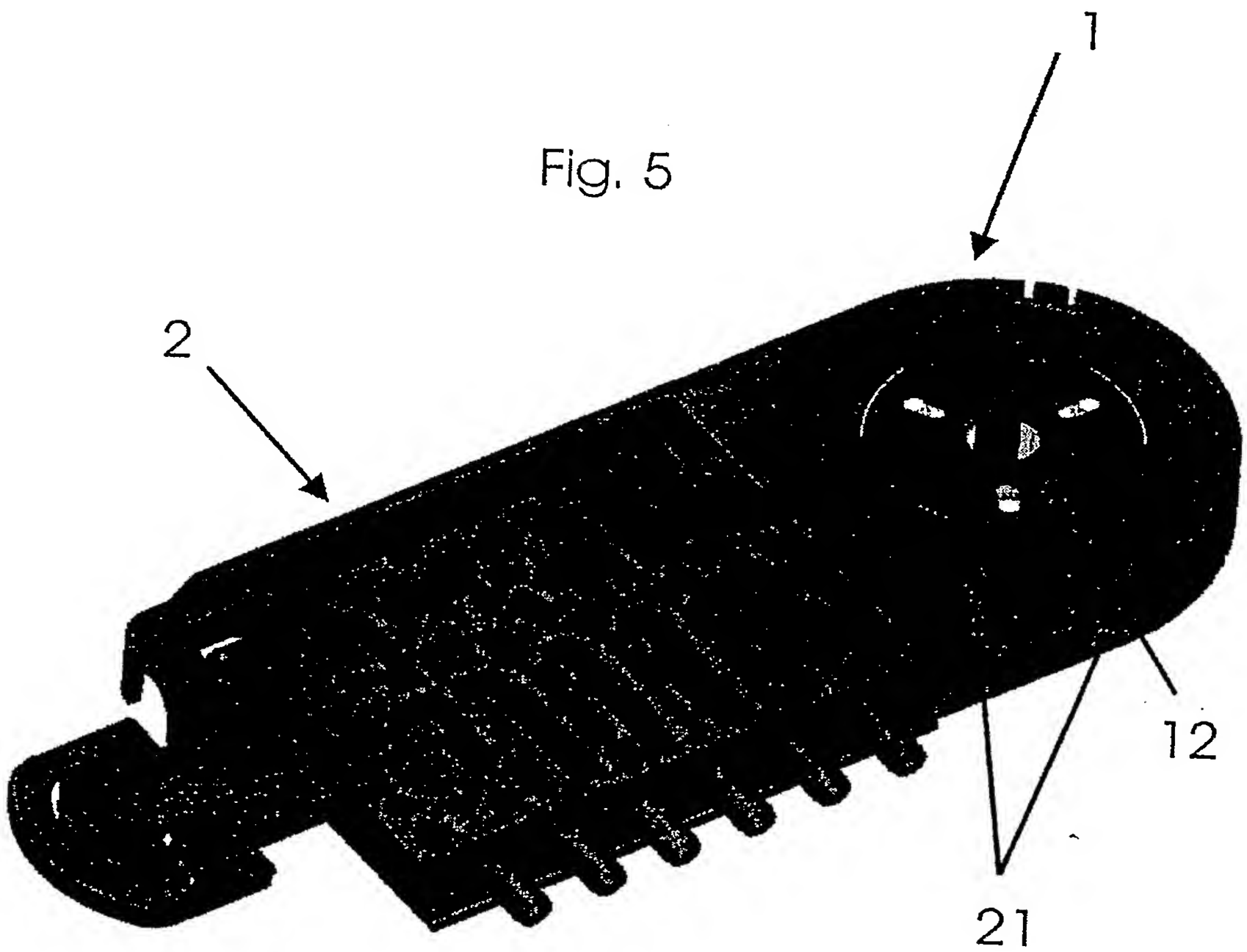

Fig. 6

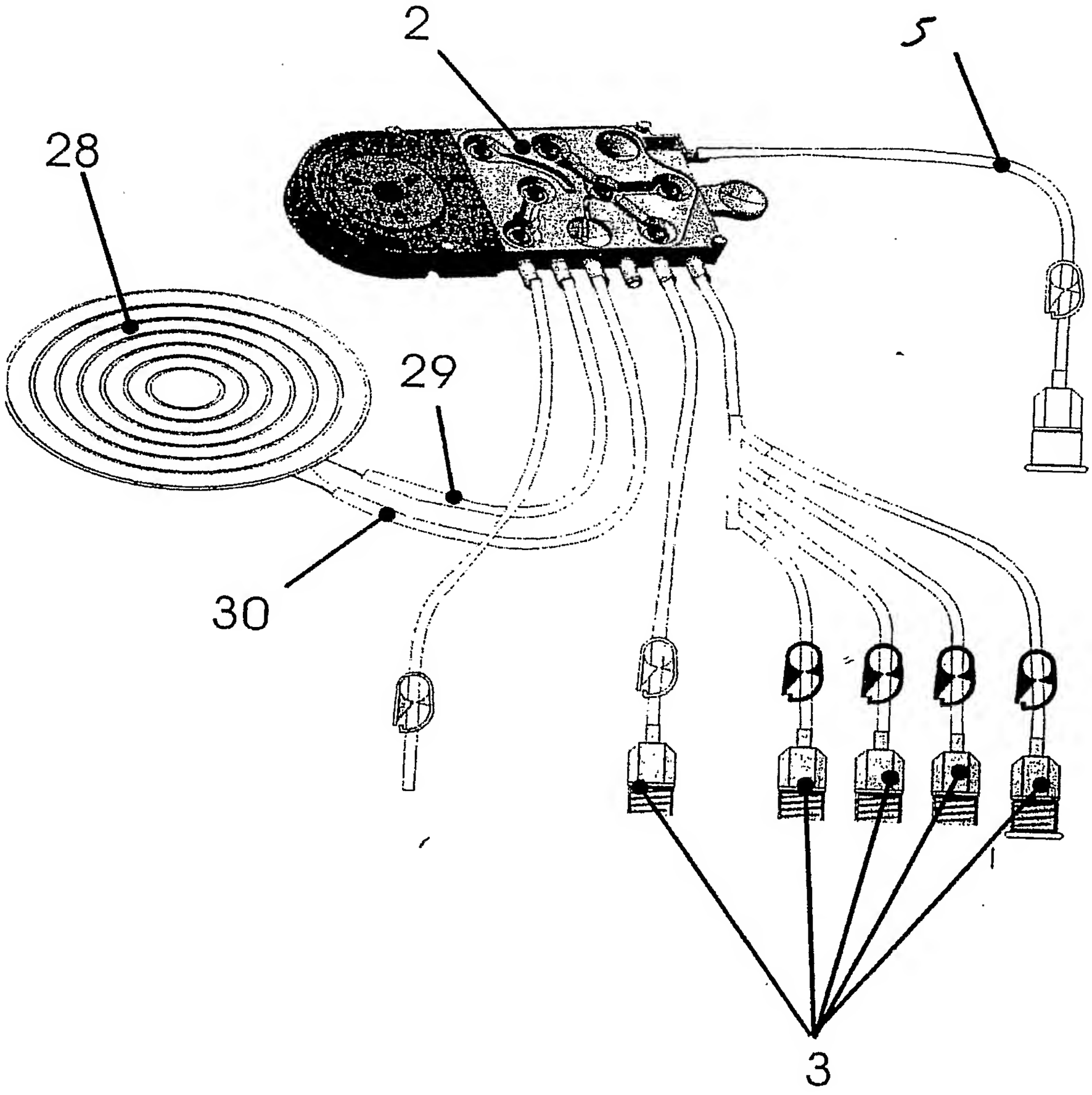

Fig. 7

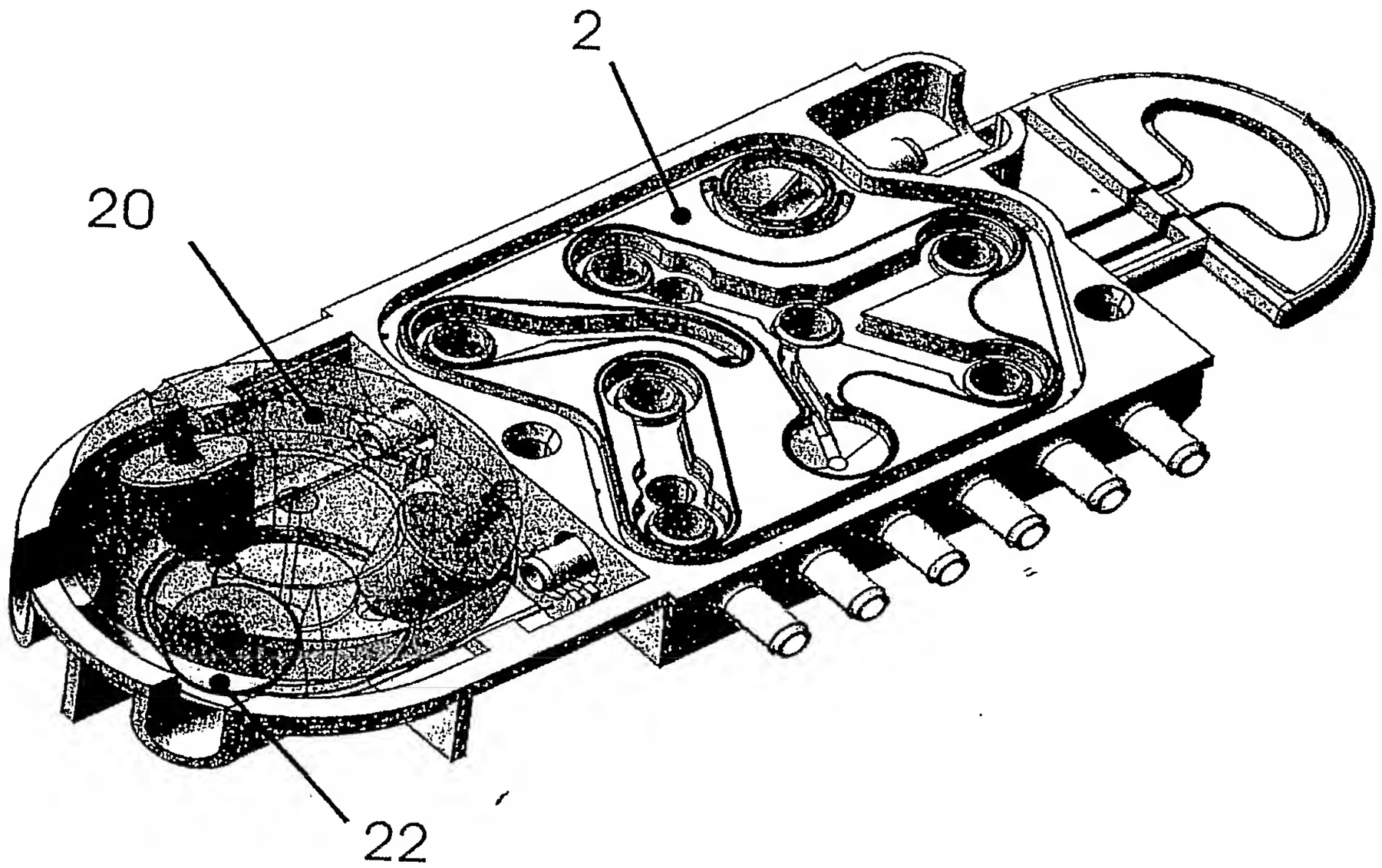

Fig. 7a

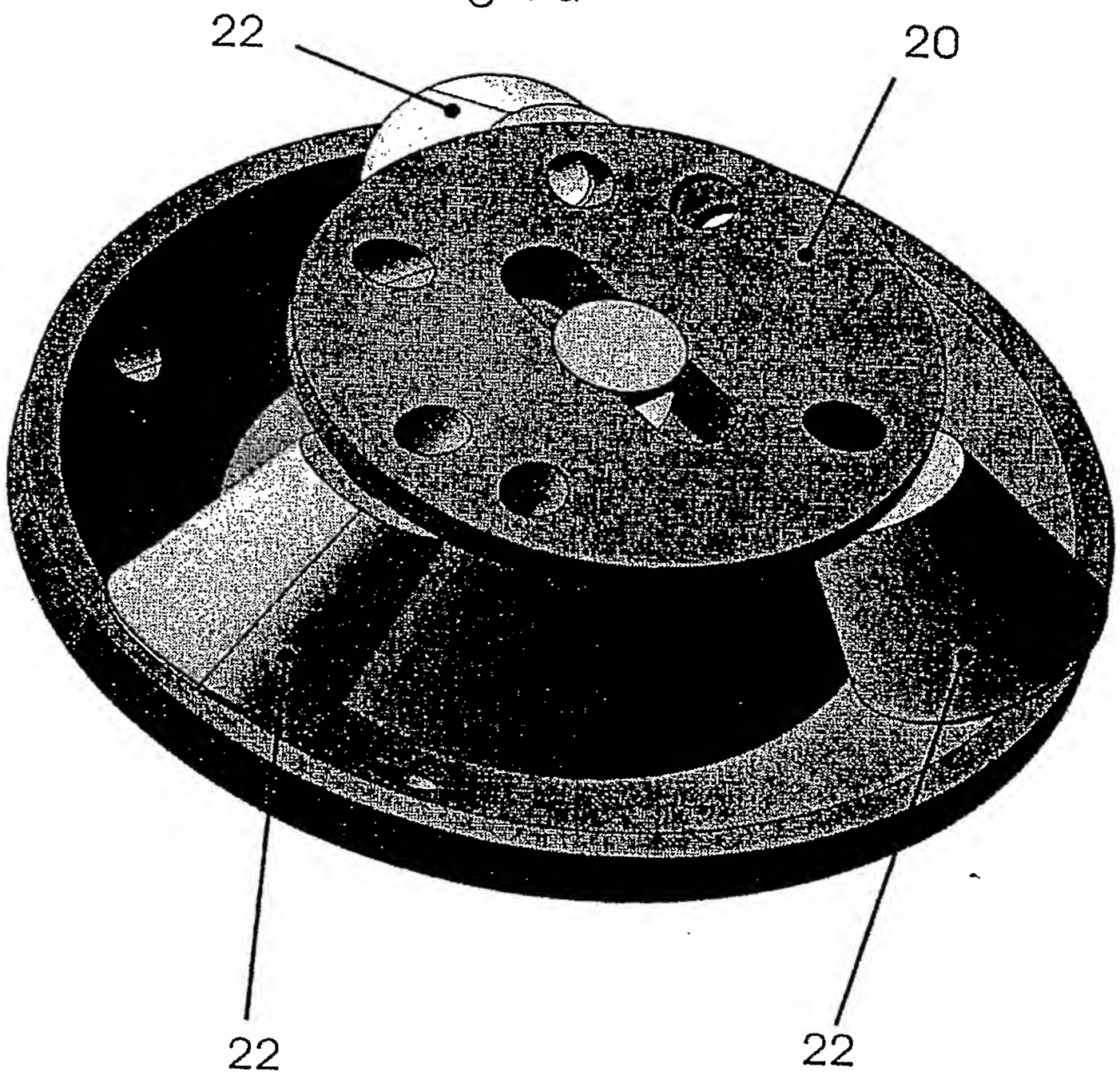

Fig. 8

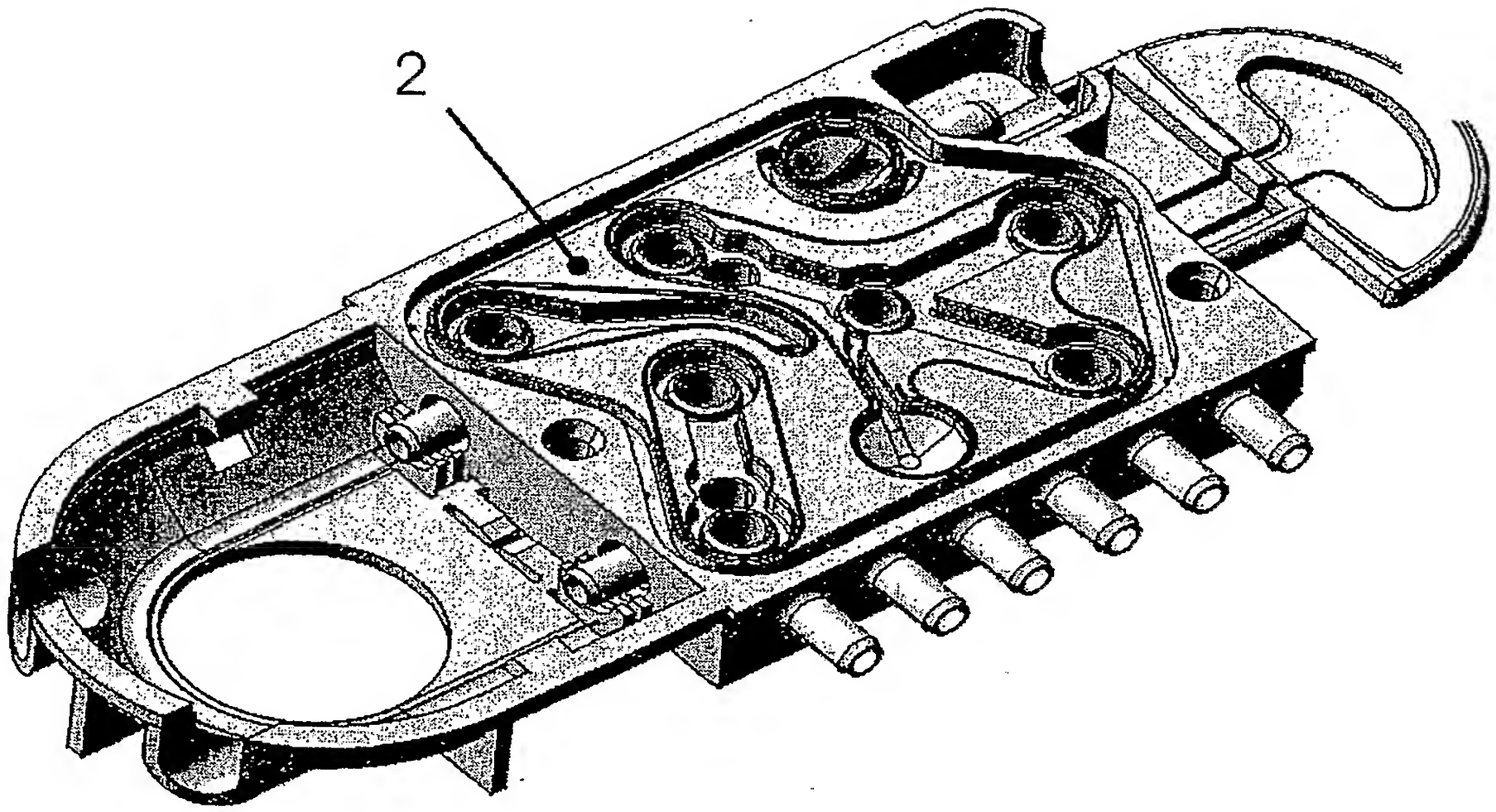

Fig. 9

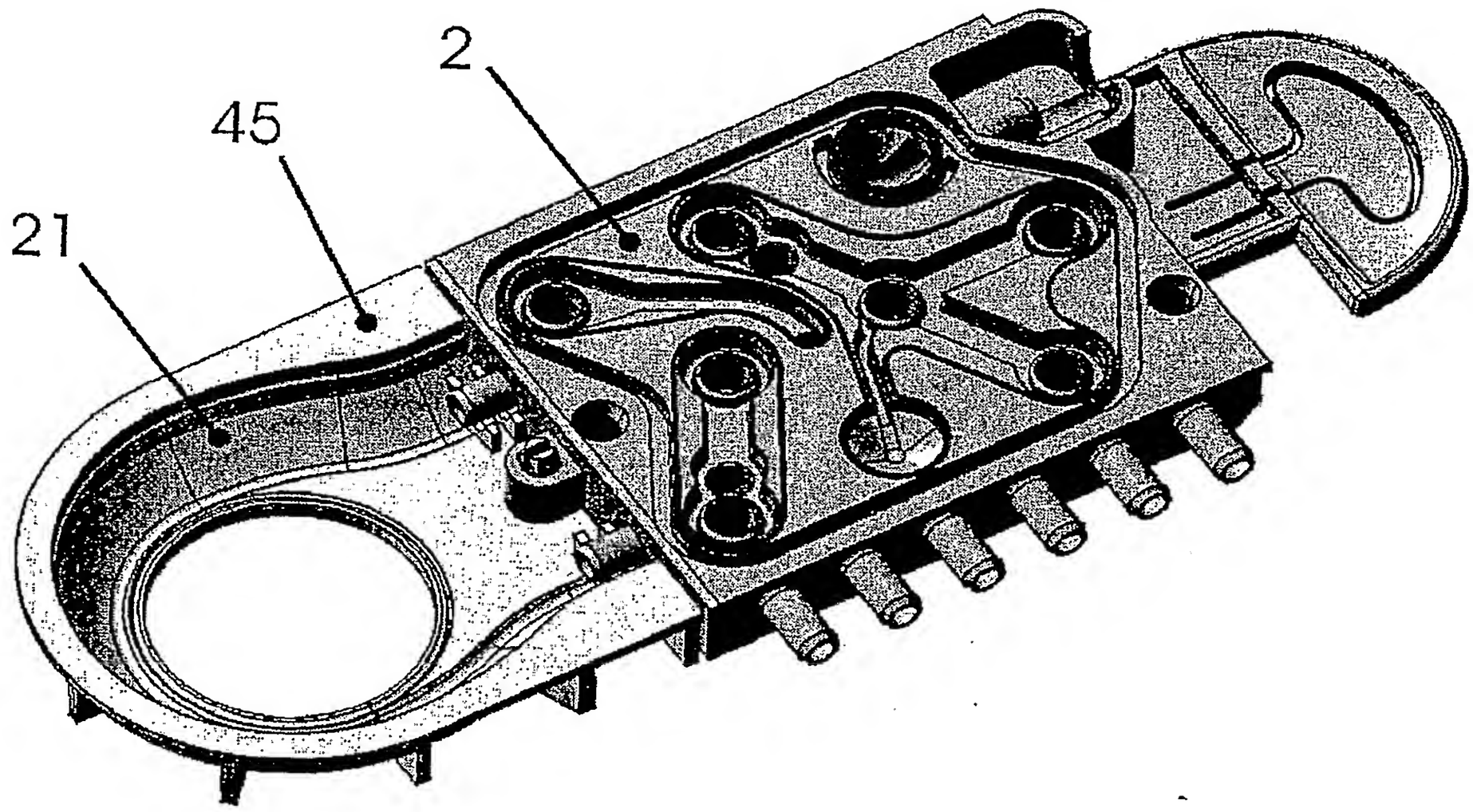

Fig. 10

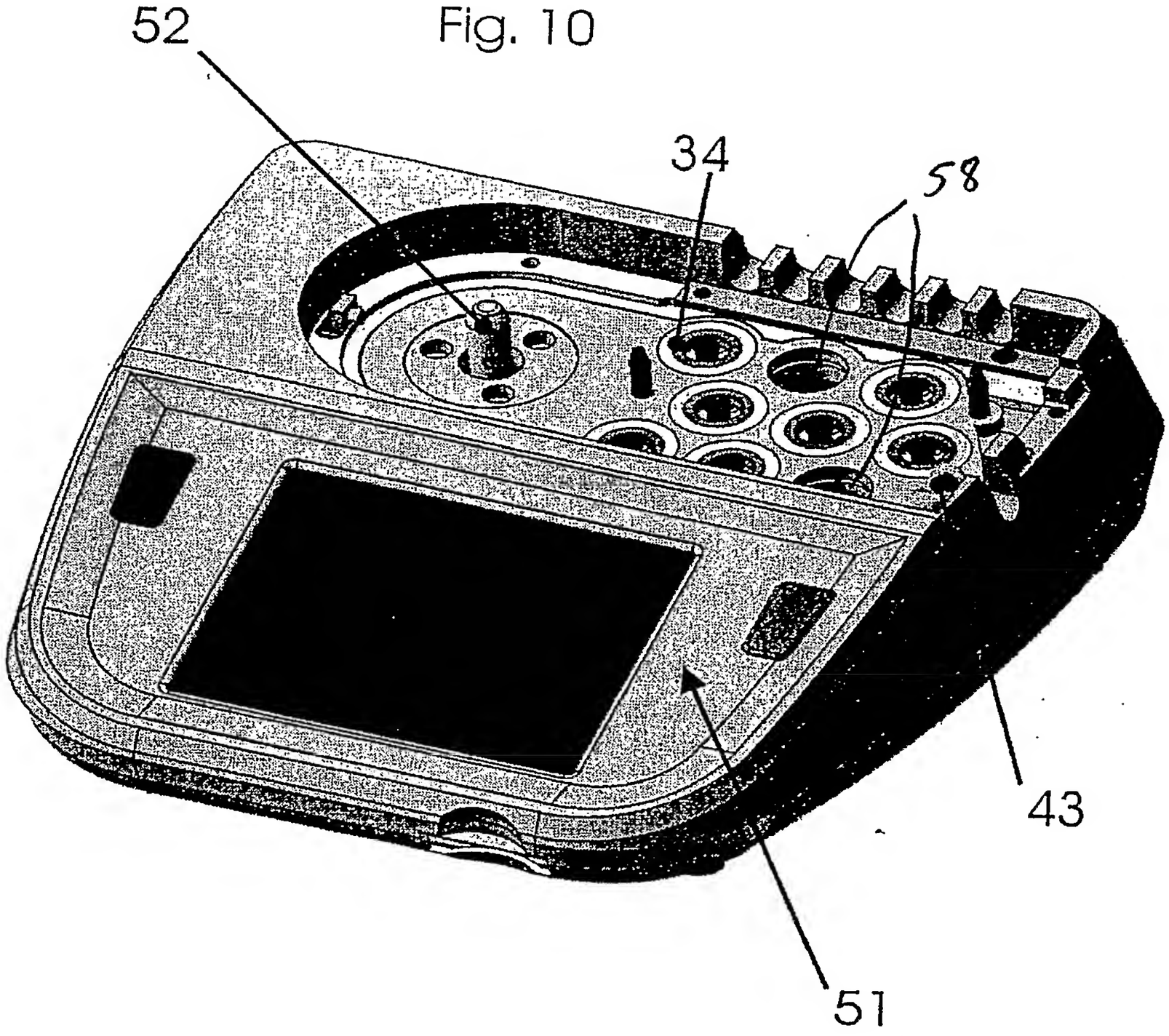

Fig. 11

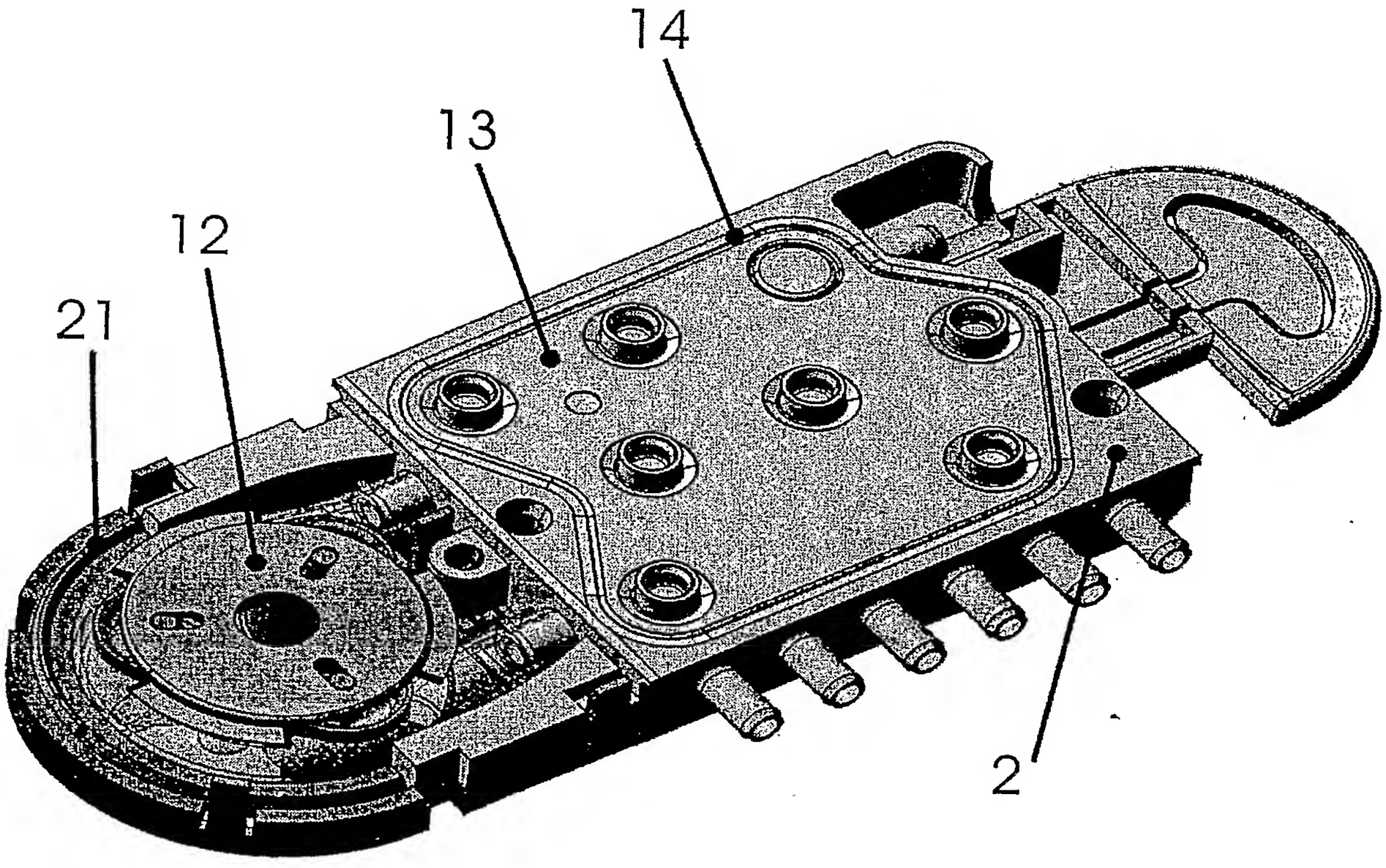

Fig. 12

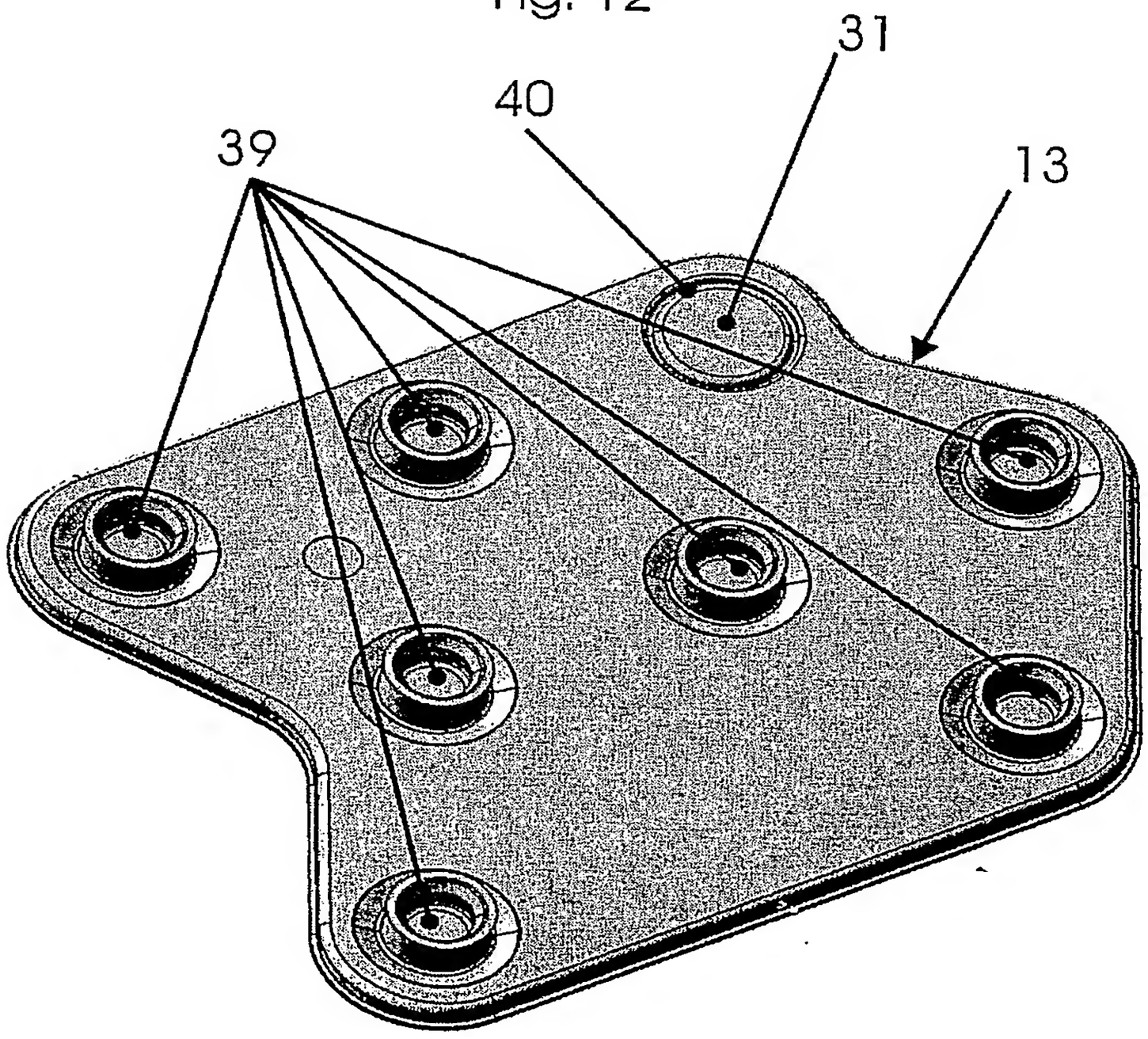

Fig. 13

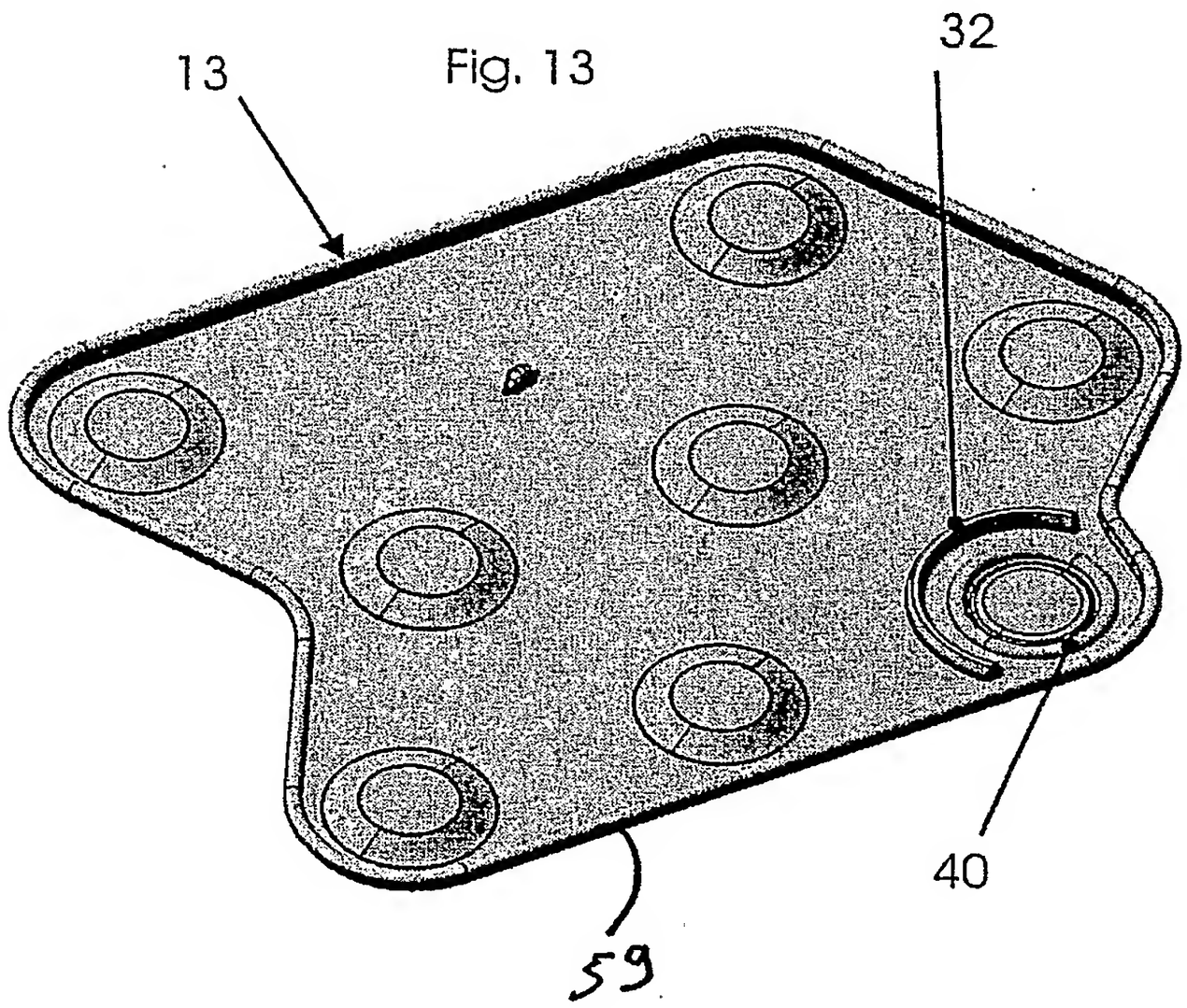

Fig. 14

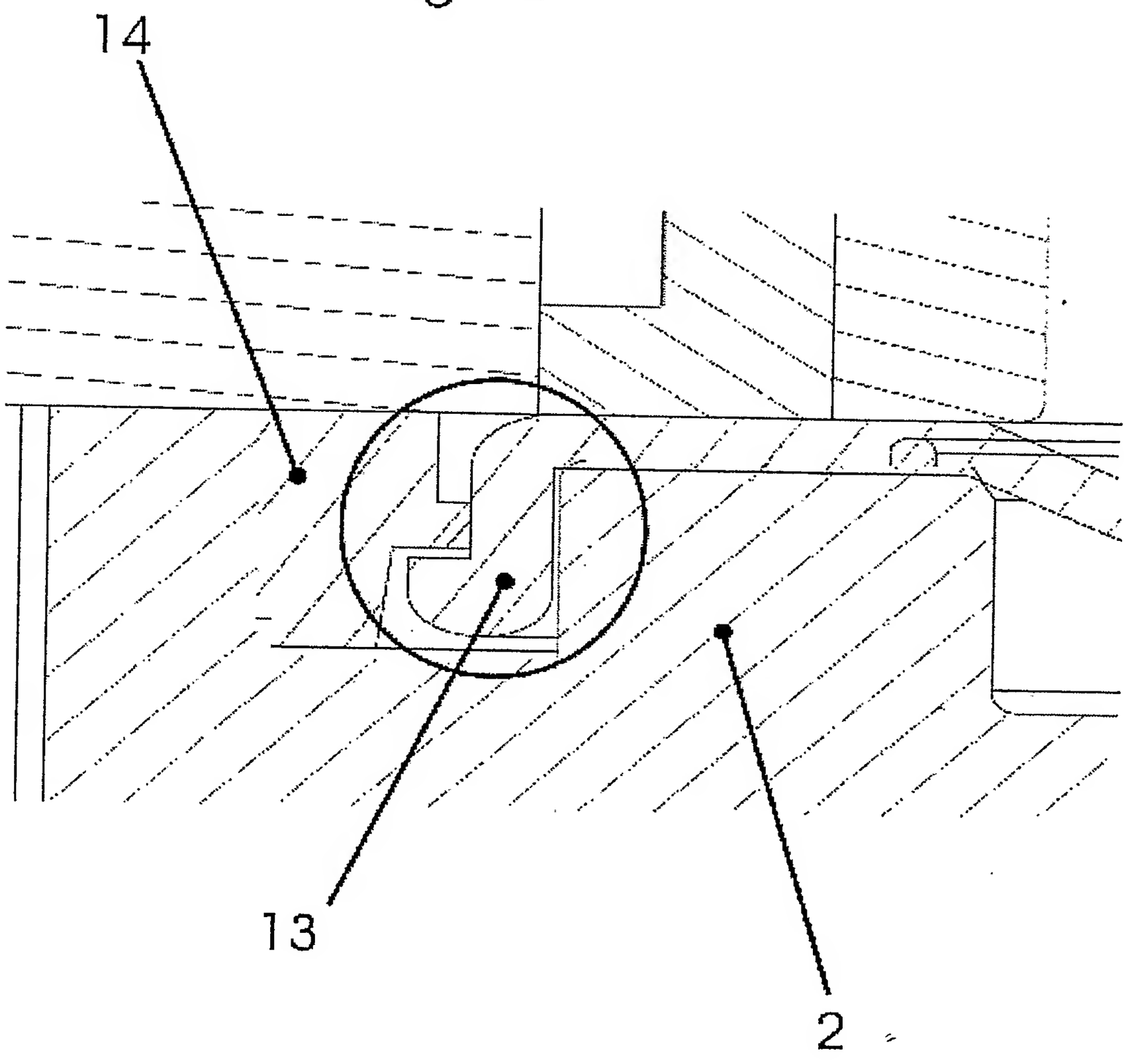

Fig. 14a

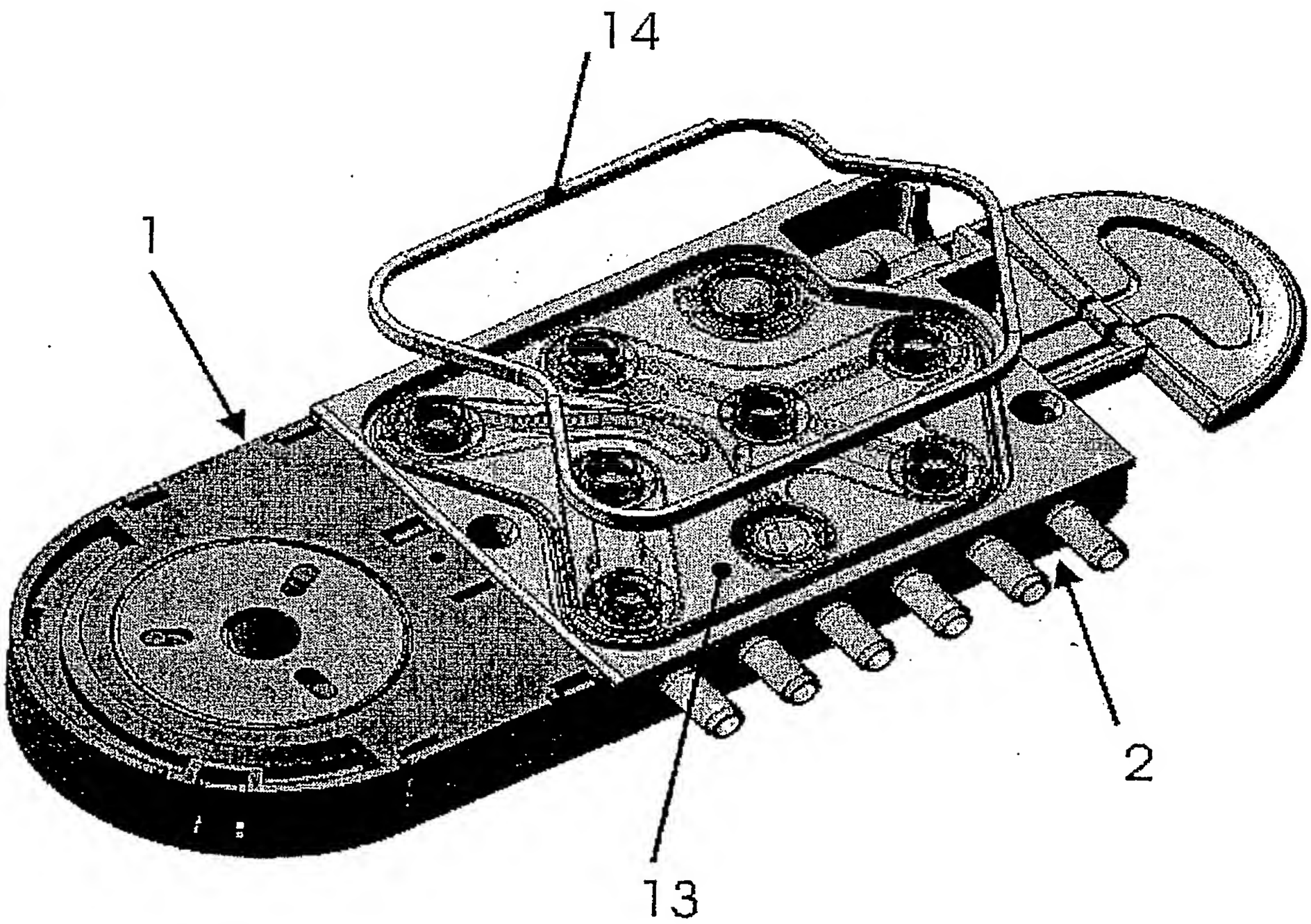

Fig. 15

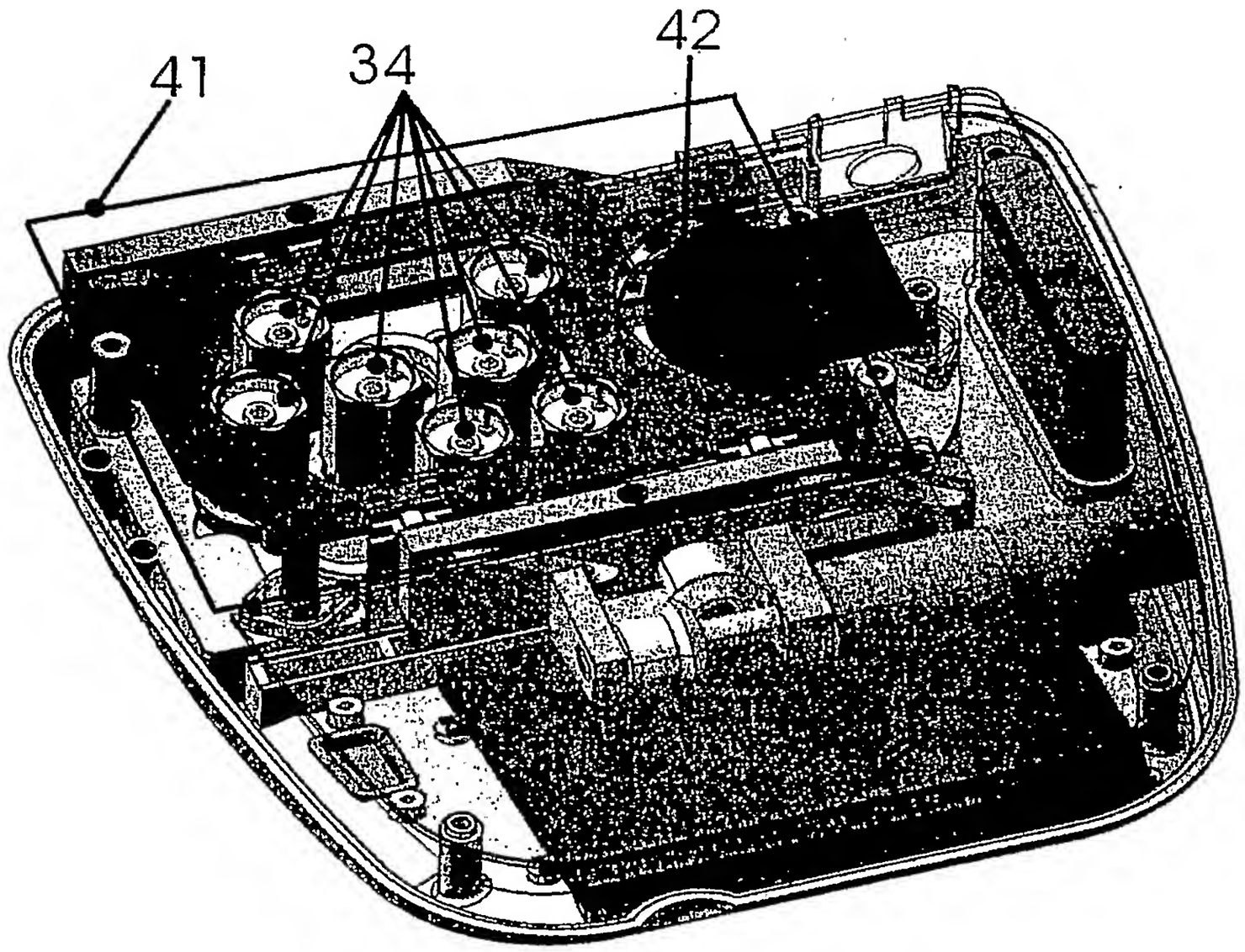

Fig. 16

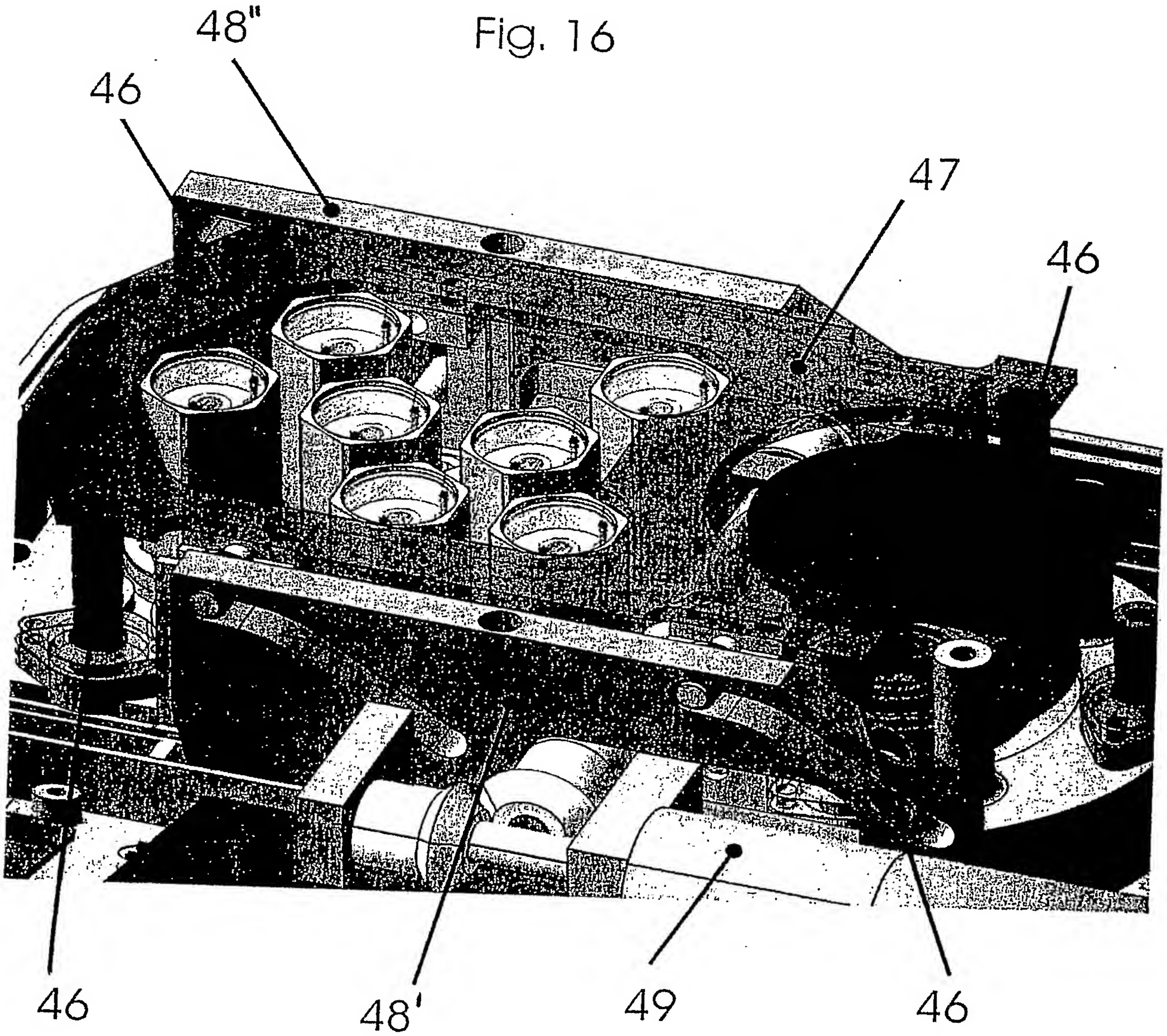

Fig. 17

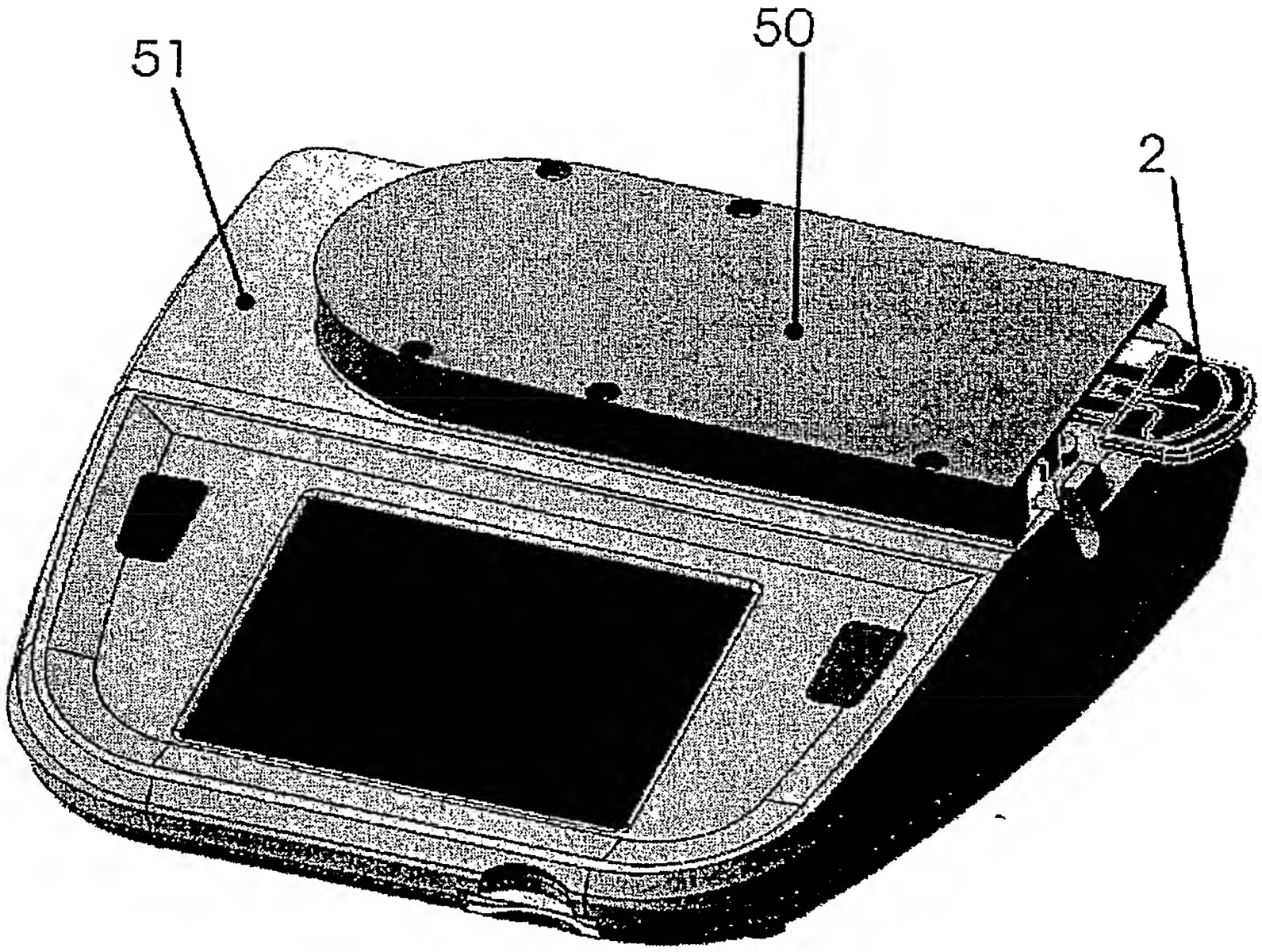

Fig. 18

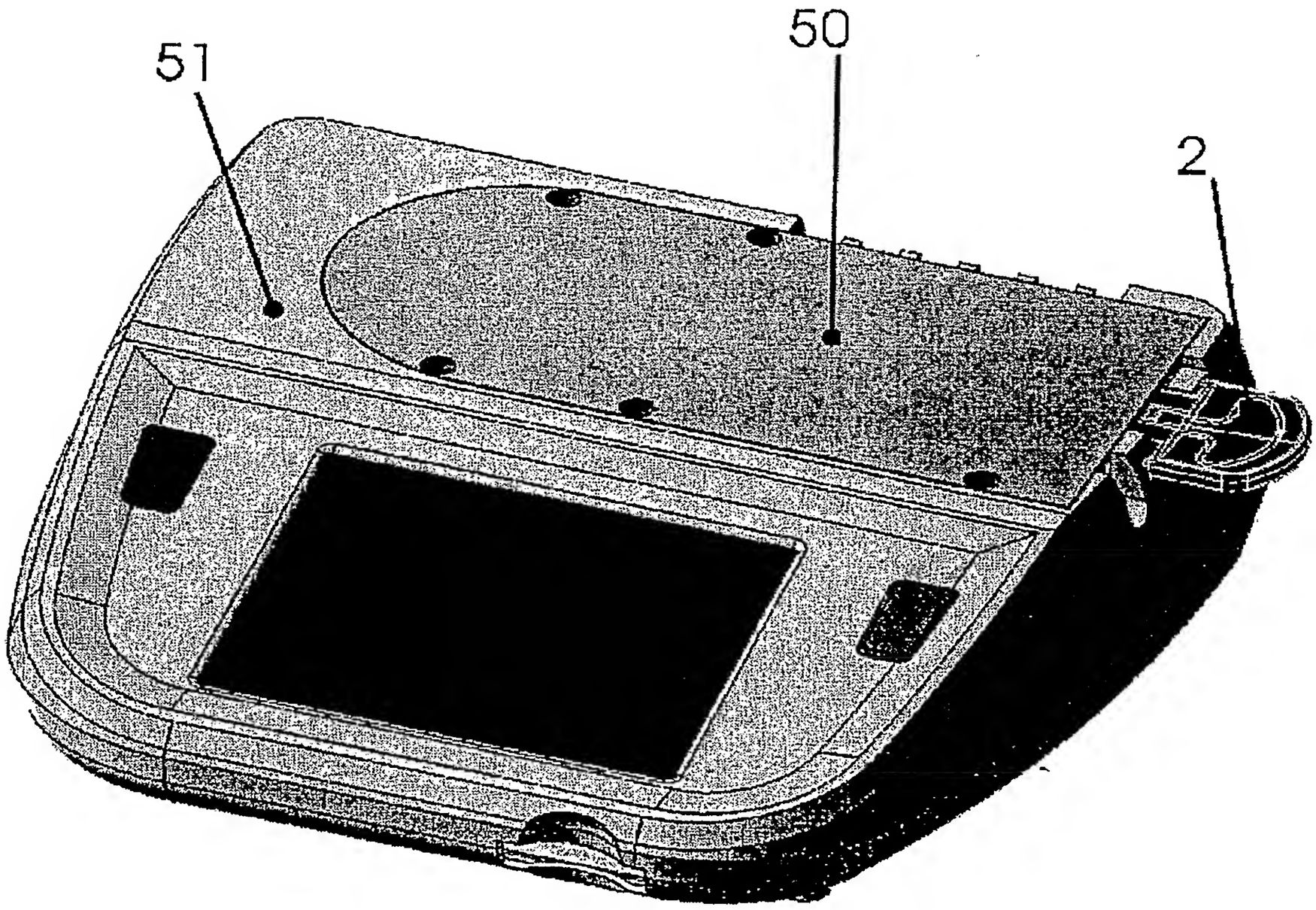

Fig. 19

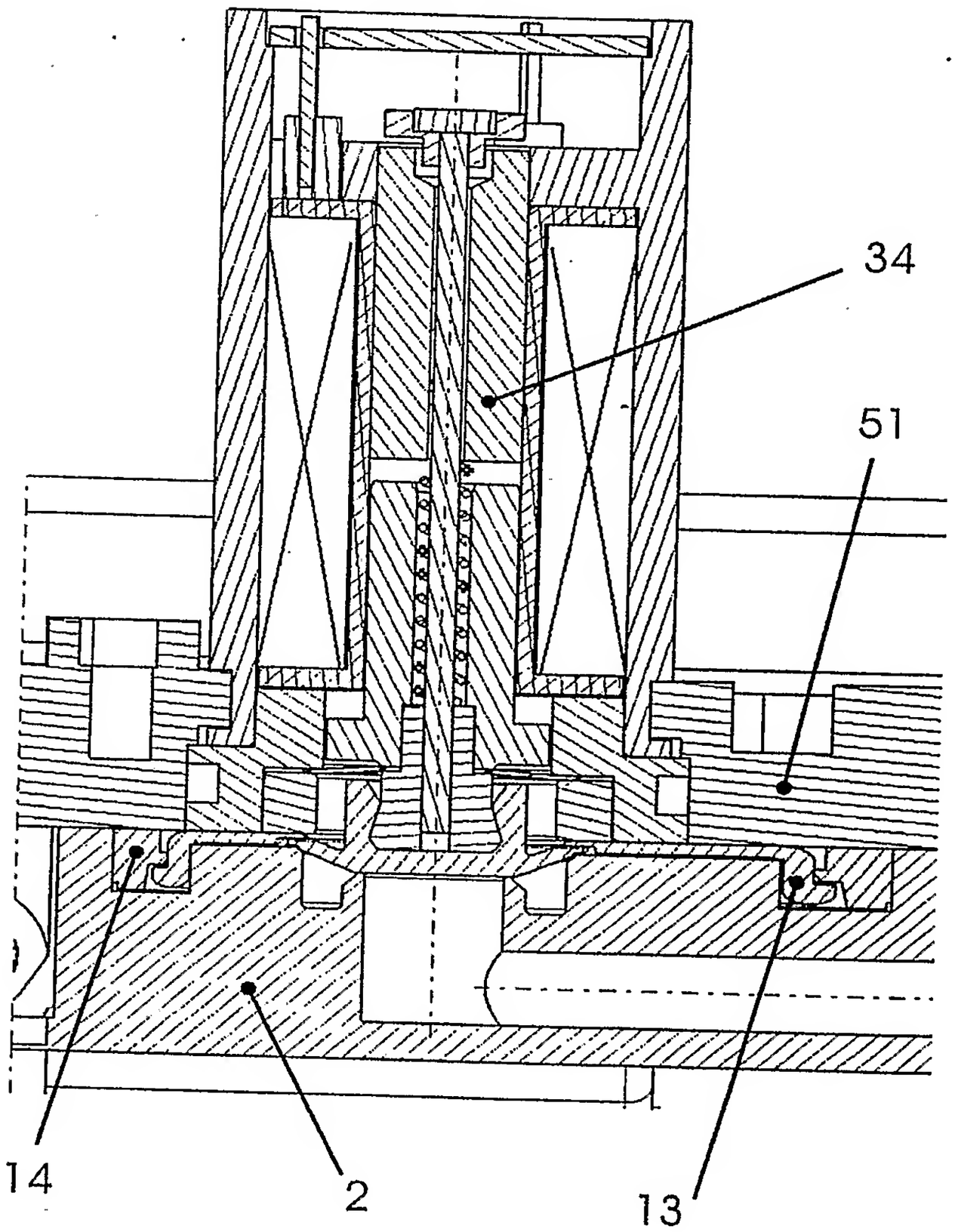

Fig. 20

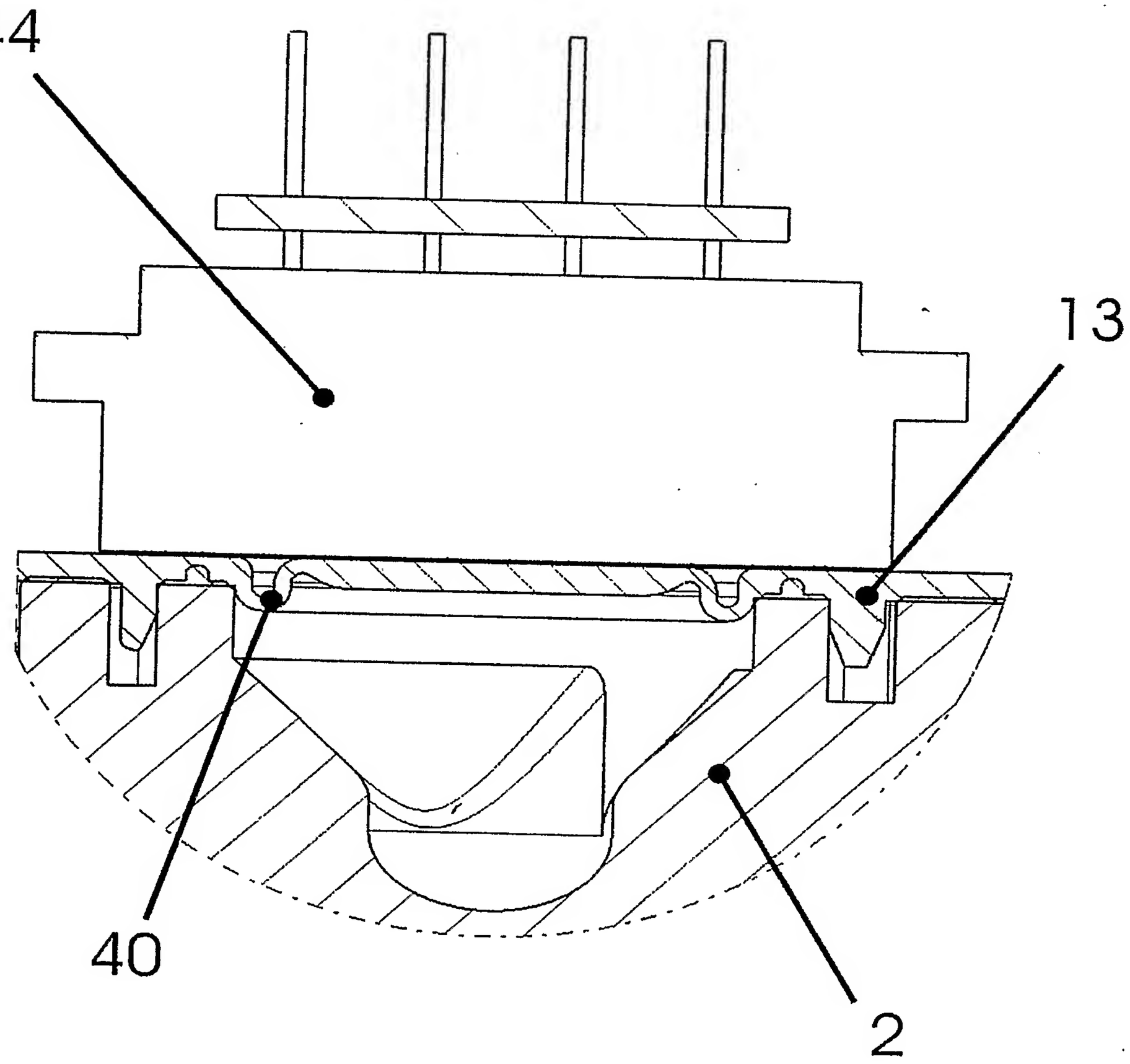

Fig. 21

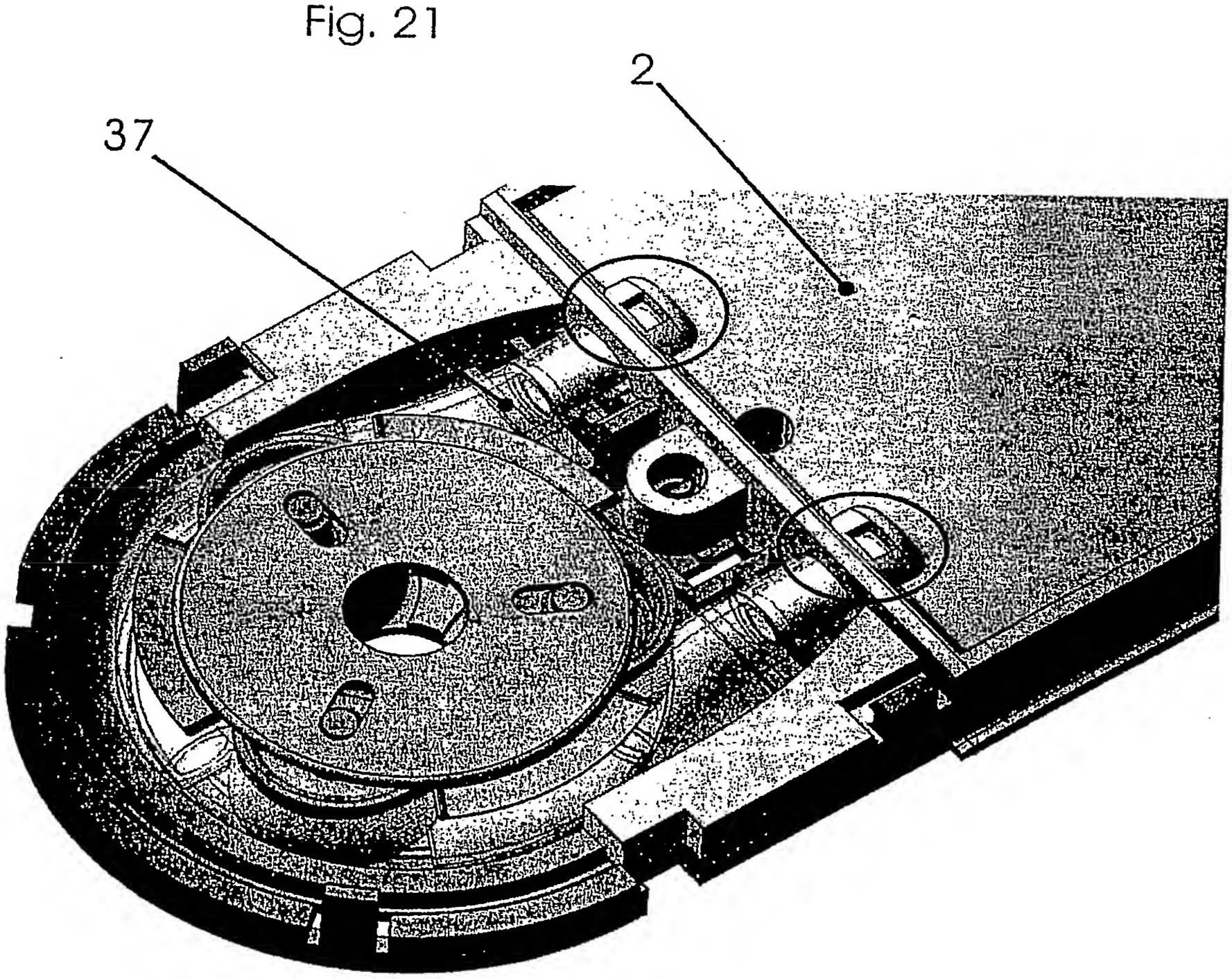

Fig. 22a

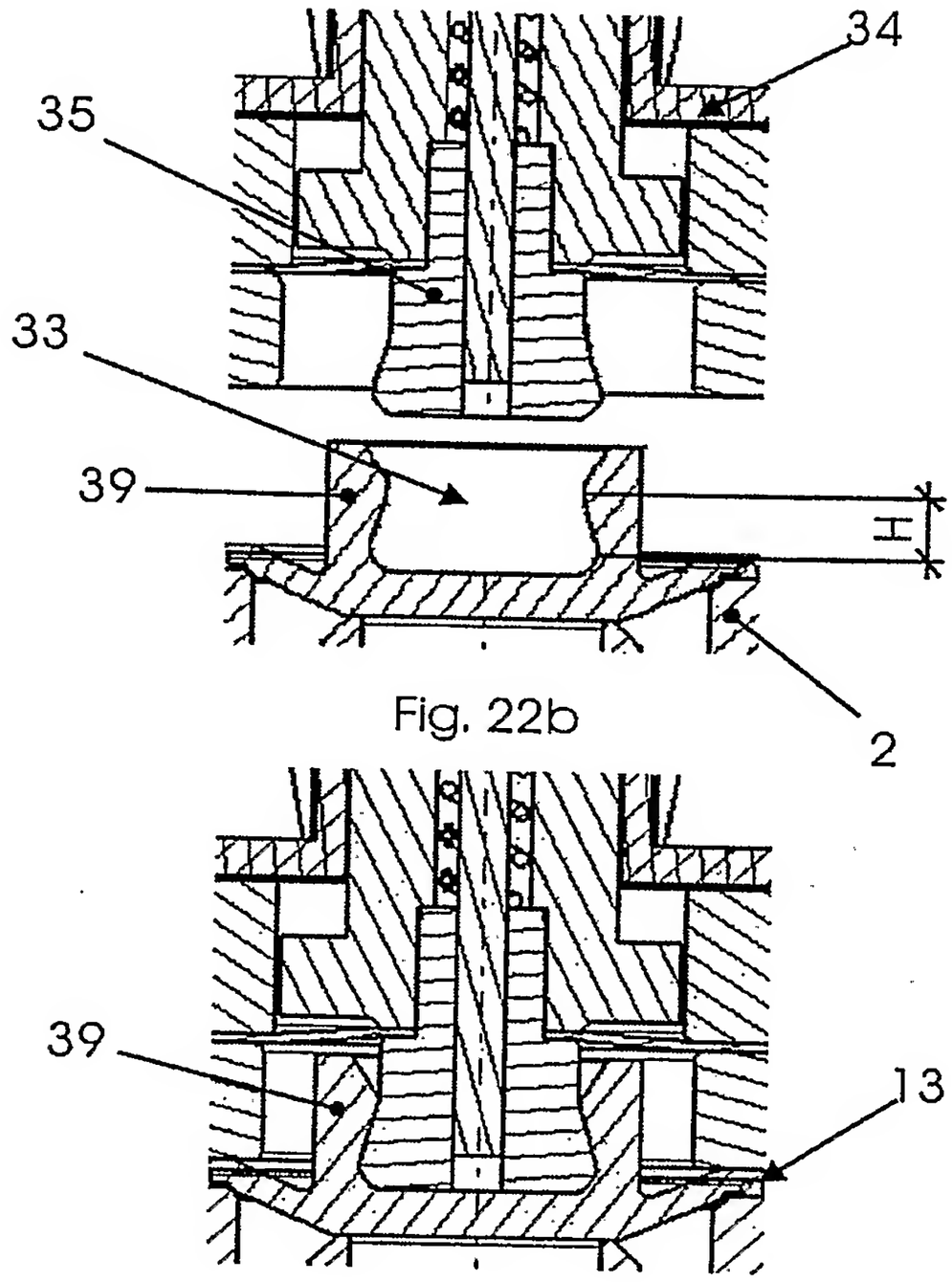

Fig. 22b

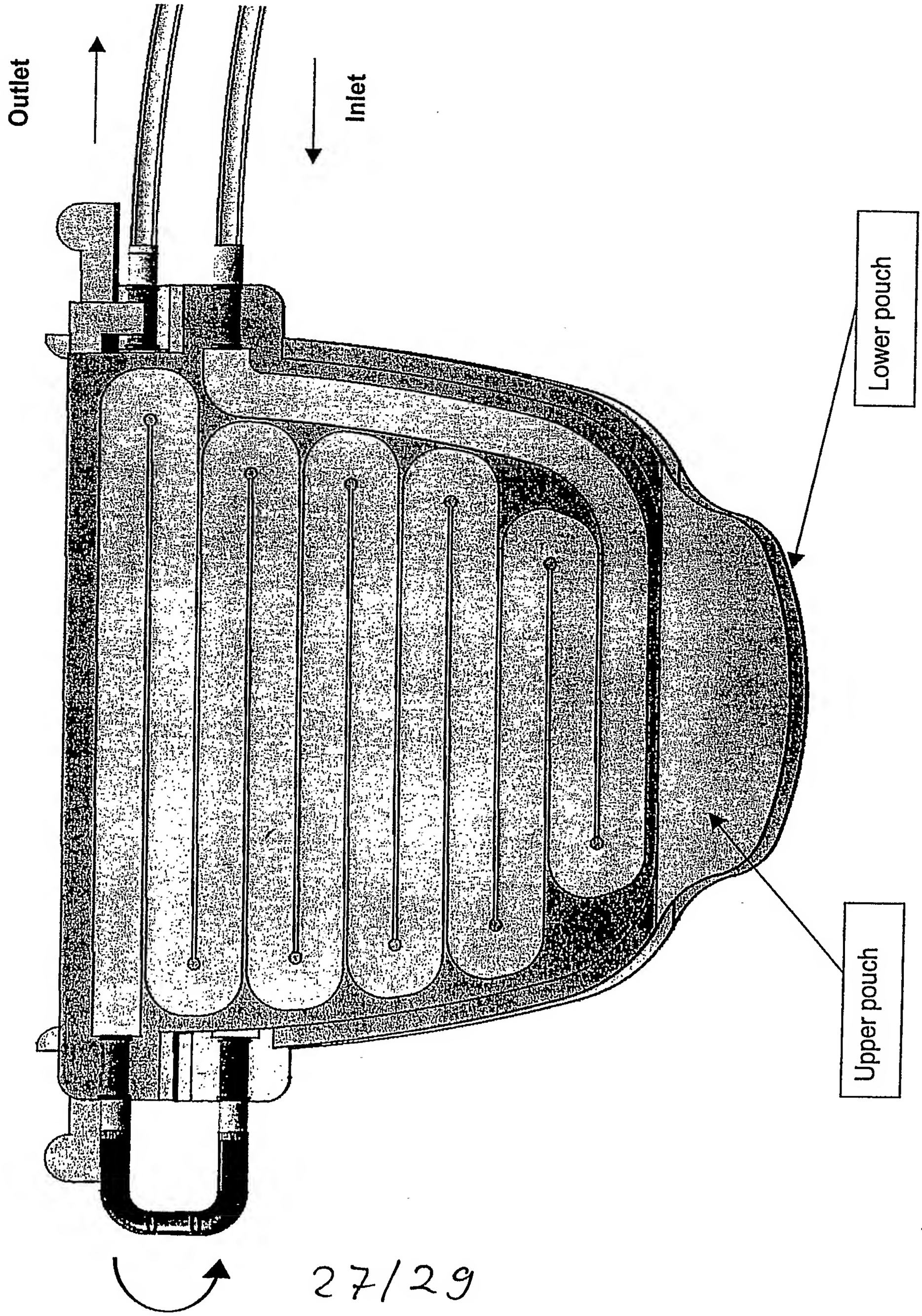

FIG. 23

FIG. 24B

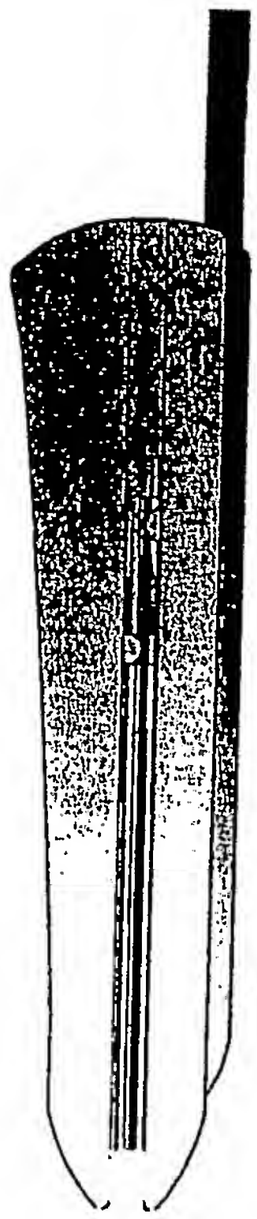

FIG. 24A

FIG. 24C

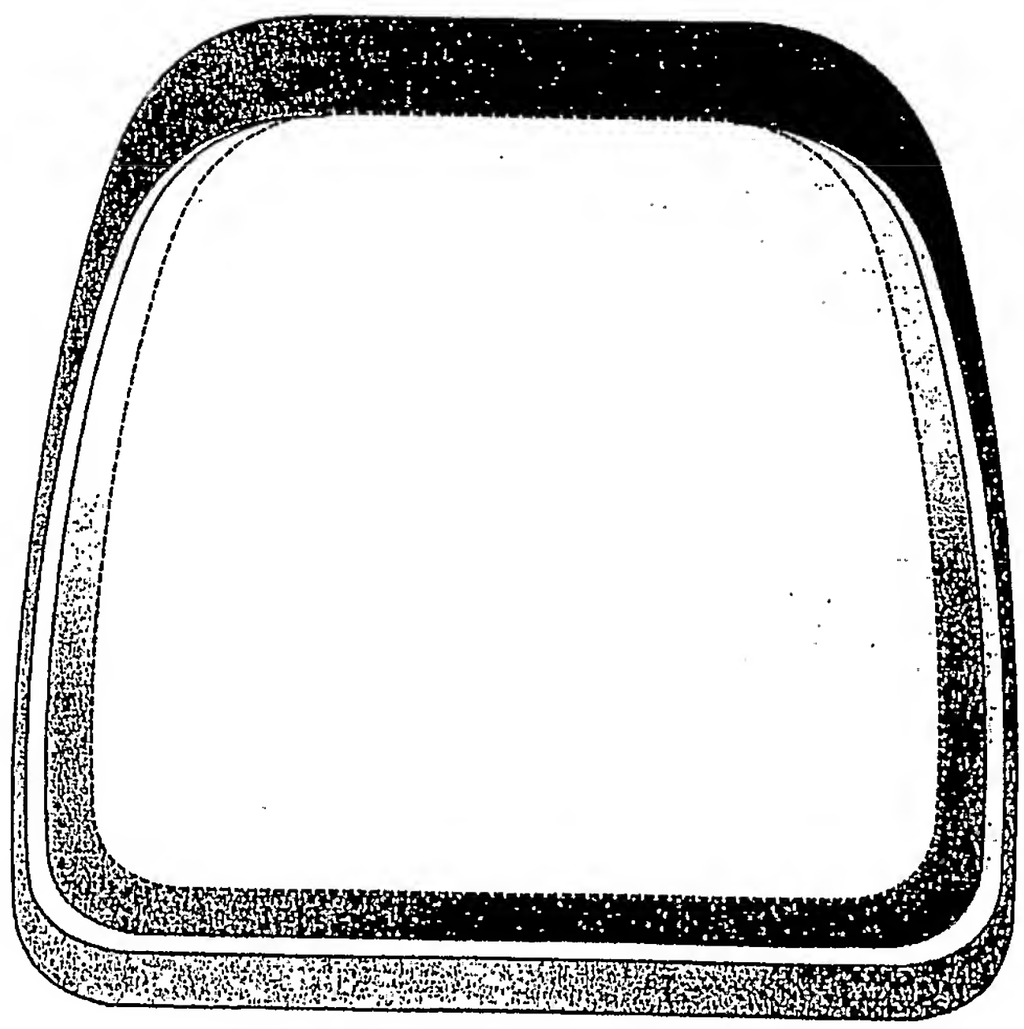

FIG. 25

DRAIN ANALISYS APD

	Vol.	Cycle 1		Vol.	Cycle 2		Vol.	Cycle 3		Vol.	Cycle 4		Vol.	Cycle 5	
[min]	[ml]	Q [l]/[min]		[ml]	Q [l]/[min]		[ml]	[l]/[min]		[ml]	Q [l]/[min]		[ml]	Q [l]/[min]	
0	2330			2752			2503			2665			2736		
1	2131	0.199		2600	0.152		2294	0.209		2490	0.175		2580	0.156	
2	1900	0.231		2375	0.225		2087	0.207		2253	0.237		2348	0.232	
3	1681	0.219		2158	0.217		1860	0.227		2035	0.218		2120	0.228	
4	1453	0.228		1941	0.217		1637	0.223		1809	0.226		1892	0.228	
5	1233	0.220		1725	0.216		1420	0.217		1585	0.224		1651	0.241	
6	1023	0.210		1499	0.226		1193	0.227		1369	0.216		1421	0.230	
7	797	0.226		1292	0.207		976	0.217		1143	0.226		1200	0.221	
8	579	0.218		1075	0.217		750	0.226		927	0.216		991	0.209	
9	367	0.212		848	0.227		532	0.218		721	0.206		784	0.207	
10	173	0.194	treshold 1	644	0.204		326	0.206	treshold 1	512	0.209	treshold 1	583	0.201	
11	72	0.101	teshold 2	437	0.207		147	0.179	treshold 2	433	0.079		404	0.179	treshold 1
12	50	0.022	Q [l]/[min]	232	0.205	treshold 1	72	0.075	Q [l]/[min]	374	0.059		302	0.102	
13	29	0.021	0.216	74	0.158	treshold 2	35	0.037	0.2142	307	0.067		228	0.074	treshold 2
14	20	0.009	0.101	39	0.035	Q [l]/[min]	4	0.031	0.075	213	0.094	treshold 2	185	0.043	Q [l]/[min]
15	4	0.016	0.017	25	0.014	0.21	0	0.004	0.024	169	0.044	Q [l]/[min]	172	0.013	0.212
16				7	0.018	0.158				121	0.048	0.2153	125	0.047	
17				0	0.007	0.0185				79	0.042		87	0.038	0.088
18										46	0.033		80	0.007	0.021
19										26	0.020		64	0.016	
20										5	0.021	0.075	52	0.012	
21										0	0.006	0.030	27	0.025	
22													7	0.020	
23													0	0.006	
24													0	0.001	

Patient BH